Exhibit 64

| | Page 1 |
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| 1 | IN THE UNITED STATES DISTRICT COURT |
| 2 | FOR THE DISTRICT OF NEW JERSEY |
| 3 | |
| 4 | |
| 5 | IN RE: JOHNSON & JOHNSON MDL NO.: |
| 6 | TALCUM POWDER PRODUCTS 16-2738 (MAS)(RLS) |
| 7 | MARKETING, SALES PRACTICES, |
| 8 | AND PRODUCTS LIABILITY |
| 9 | LITIGATION |
| 10 | |
| 11 | |
| 12 | EXPERT DEPOSITION OF |
| 13 | BERNARD L. HARLOW, PHD |
| 14 | |
| 15 | Tuesday, April 9, 2024 |
| 16 | 9:27 a.m. Eastern Time |
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| 19 | |
| 20 | |
| 21 | |
| 22 | |
| 23 | Reported by: Denise Dobner Vickery, CRR, RMR |
| 24 | JOB NO.: 6474272 |
| | |

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| 1 | 1 age 2 | 1 | APPEARANCES: |
| 2 | | 2 | |
| 3 | | 3 | For New Jersey Plaintiffs: |
| 4 | | 4 | ANAPOL WEISS |
| 5 | | 5 | BY: TRACY A. FINKEN, ESQ. |
| 6 | | 6 | One Logan Square |
| 7 | | 7 | 130 N. 18th Street, Suite 1600 |
| 8 | Tuesday, April 9, 2024 | 8 | Philadelphia, PA 19103 |
| 9 | 9:27 a.m. Eastern Time | | 215.735.0773 |
| 1 | 9.27 a.m. Eastern Time | 9 | |
| 10 | Engant Danasition of DEDNADD I | 10 | tfinken@anapolweiss.com |
| 11 | Expert Deposition of BERNARD L. | 11 | |
| 12 | HARLOW, PHD, held at the offices of: | 12 | |
| 13 | A GALGE A ETT O GEREN A A R | 13 | |
| 14 | ASHCRAFT & GEREL LLP | 14 | For Defendants Johnson & Johnson and Johnson & |
| 15 | 1825 K Street NW | 15 | Johnson Consumer Inc.: |
| 16 | Suite 700 | 16 | SHOOK HARDY & BACON LLP |
| 17 | Washington, DC 20006 | 17 | BY: MARK C. HEGARTY, ESQ. |
| 18 | | 18 | 2555 Grand Blvd. |
| 19 | | 19 | Kansas City, MO 64108 |
| 20 | Pursuant to notice, before Denise | 20 | 816.474.6550 |
| 21 | Dobner Vickery, Certified Realtime Reporter, | 21 | mhegarty@shb.com |
| 22 | Registered Merit Reporter, and Notary Public in | 22 | |
| 23 | and for the District of Columbia. | 23 | |
| 24 | | 24 | |
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| 2 3 4 5 6 7 | For Plaintiffs: LEVIN PAPATONIO RAFFERTY PROCTOR BUCHANAN O'BRIEN BARR & MOUGEY, PA BY: CHRISTOPHER V. TISI, ESQ. 316 South Baylen Street, Suite 600 | 2 3 4 5 6 7 8 | INDEX EXAMINATION OF BERNARD L. HARLOW, PHD BY MR. HEGARTY AFTERNOON SESSION 218 BY MR. TISI 418 FURTHER BY MR. HEGARTY 500 |
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| 11 | EXHIBIT 11 Genital Powder Use and Risk of 166 | 11 | Correlative Light and Scanning |
| 12 | Epithelial Ovarian Cancer in the | 12 | Electron Microscopy, McDonald et al |
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| 16 | Exposure and Risk of Ovarian Cancer | 16 | Replicability, 1 August 2021, ASA |
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| 21 22 | EXHIBIT 14 Serous Ovarian Cancer Caused by 194 Exposure to Asbestos and Fibrous | 21 22 | and Ovarian Cancer Risk, Examining the Evidence, Gossett and del Carmen |
| 23 | Talc in Cosmetic Talc Powders - | 23 | , |
| 24 | A Case Series, Steffen et al Feb 2000 | 24 | JAMA January 7, 2020 |
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| | EXHIBIT 15 Talc/FDA Website. What's New 245 | $\frac{1}{2}$ | EXHIBIT 28 Comment & Response, Genital 379 |
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| 5 | | 6 | meta-analysis of epidemiologic evidence on the association between |
| 6 | November 17, 1994 and May 13, 2008 | | perineal use of talc powder and risk |
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| 12 | Editorial Board, February 28, 2024 | 12 | of talc powder and risk of ovarian |
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| 14 | Use of Perineal Talcum Powder | 14 | |
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| 17 | Woolen et al, February 2, 2022 | 17 | |
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| 20 | Subtype, Gates et al, 2010 | 20 | |
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| 3 | EXHIBIT P1 The association between douching, 421 | 3 | BERNARD L. HARLOW, PHD |
| 4 | genital talc use, and the risk of | 4 | called for examination, and, after having been |
| 5 | prevalent and incident cervical | 5 | duly sworn, was examined and testified as |
| 6 | cancer, O'Brien et al, 2021 | 6 | follows: |
| 7 | EXHIBIT P2 A Case-Control Study of 429 | 7 | Tollows. |
| 8 | Borderline Ovarian Tumors: | 8 | EXAMINATION |
| 9 | The Influence of Perineal | 9 | |
| 10 | Exposure to Talc, Harlow | 10 | BY MR. HEGARTY: |
| 11 | and Weiss, February 28, 1989 | 11 | Q. Good morning, Dr. Harlow. |
| 12 | EXHIBIT P3 Perineal Exposure to Talc and 432 | 12 | A. Good morning. |
| 13 | Ovarian Cancer Risk, Harlow et al | 13 | Q. Would you please tell us your full |
| 14 | July 1992 | | name? |
| 15 | EXHIBIT P4 Talc: Consumer Uses and Health 437 | 15 | A. Bernard L. Harlow. |
| 16 | Perspectives, C. Jelleff Carr | 16 | Q. Have you ever given a deposition |
| 17 | October 1, 1994 | 1 | before? |
| 18 | EXHIBIT P5 A Review of Perineal Talc 443 | 18 | A. I have not. |
| 19 | Exposure and Risk of Ovarian Cancer, | 19 | Q. Have you ever read any deposition |
| 20 | Harlow and Hartge, October 1, 1994 | | transcript? |
| 21 | EXHIBIT P6 Genital Talc Exposure and Risk 454 | 21 | A. Yes. |
| 22 | of Ovarian Cancer, | 22 | Q. How many deposition transcripts have |
| 23 | Cramer et al, 1999 | | you read prior to today? |
| 24 | Cramer et al, 1777 | 24 | A. Maybe three. |
| 1 2 3 4 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 | EXHIBIT P7 Interpretation of Epidemiologic 467 Studies on Talc and Ovarian Cancer, Rothman et al, November 28, 2000 EXHIBIT P8 Association of genital talc and 477 douche use in early adolescence or adulthood with uterine fibroids diagnoses, Ogunsina et al, December 2023 EXHIBIT P9 Federal Register, 40 CFR 482 Part 751 Asbestos Part 1; Chrysotile Asbestos; Regulation of Certain Conditions of Use Under the Toxic Substances Control Act (TSCA), March 28, 2024 | 3 4 5 6 7 8 9 10 11 12 13 14 15 16 | Q. Do you recall the deponents in those transcripts? A. I believe I read I read more Moor Q. You can't look at him. A. Okay. I'm just I'm just Moorman I believe I read. Q. Patricia Moorman? A. Patricia Moorman. I can't remember her name. Q. It's okay if you cannot remember. A. I can't remember. I can't remember the names. Q. You can only recall Dr. Moorman's? A. I recall Dr. Moorman, and there was one that was more recent. I mean, I could I just I can't remember the name. MR. TISI: Can I just and let |
| 19 | | 19 | me just say this because this is the |
| 20 | | 20 | first time you have testified, and I just |
| 21 | | 21 | want to make sure. |
| 22 | | 22 | He's going to be asking |
| 23 | | 23 | questions. Normally we kind of |
| 24 | | 24 | anticipate questions and we talk over |
| | | ∟ | |

| | D 11 | | D 46 |
|-------|---|----|---|
| 1 | Page 14 each other. | 1 | Page 16 Q. Other than those two notebooks, did |
| 2 | It makes the record a lot | | you bring any other materials with you to today's |
| 3 | easier for for Denise here if you | 3 | deposition? |
| 4 | allow allow Mr. Hegarty to finish his | 4 | A. No. |
| 5 | question and then give an answer, and I | 5 | Q. Did you prepare any notes in |
| 6 | will make sure that Mr. Hegarty lets you | 6 | connection with your work on this case? |
| 7 | finish your answer before he starts his | 7 | A. No, I did not. |
| 8 | next question. | 8 | Q. Did you prepare any other |
| 9 | THE WITNESS: Sure. | 9 | documents or let me start over. |
| 10 | MR. HEGARTY: And I will cover | 10 | Did you prepare any documents |
| 11 | that, too, but thank you. | 11 | besides your expert report for purposes of your |
| 12 | THE WITNESS: I'm sorry that | | work on this case? |
| 13 | I forgot the name. | 13 | A. No, I did not. |
| 14 | BY MR. HEGARTY: | 14 | Q. Who is your current employer? |
| 15 | Q. When did you read Dr. Moorman's | 15 | A. Boston University School of Public |
| 16 | deposition transcript? | 16 | Health. |
| 17 | A. Probably within the last month. | 17 | Q. Do you have a separate personal |
| 18 | Q. Who did you receive that transcript | 18 | consulting business for litigation like an LLC? |
| 19 | and the other two transcripts from? | 19 | A. I do have an LLC. |
| 20 | A. From Dr I mean, Mr. Tisi. | 20 | Q. Do you run your expert witness work |
| 21 | Q. Did you make a request for those | 21 | through that LLC? |
| 22 | transcripts? | 22 | A. I I must. I must. |
| 23 | A. I believe I indicated that it would | 23 | Q. What is the name of that LLC? |
| 24 | be helpful, since I had never been deposed before, | 24 | A. Bernard L. Harlow. |
| | Page 15 | | Page 17 |
| 1 | to have a sense of the process. | 1 | Q. How long have you had that LLC? |
| 2 | Q. What Mr. Tisi just said and as you | 2 | A. About six months. |
| | just mentioned the process, it's important that | 3 | Q. Did you set that LLC up in |
| | you and I speak one at a time, that we speak | 4 | connection with your work on this litigation? |
| 1 | audibly, and that you understand the questions | 5 | A. Yes. |
| 1 | that I ask before you answer. | 6 | Q. Do the fees that you earn as an |
| 7 | Are you good with all of those sort | | expert witness go directly to you? |
| | of ground rules? | 8 | A. Yes. |
| 9 | A. Yes. | 9 | Q. Do you have any other sources of |
| 10 | · · · · · · · · · · · · · · · · · · · | | income besides the salary you get from Boston |
| | to today's deposition? | | University and whatever you earn as an expert |
| 12 | A. Yes. | | witness? |
| 13 | Q. What documents did you bring? | 13 | A. No. |
| 14 | A. Manuscripts of previously published | 14 | Q. You are charging Mr. Tisi and other |
| | papers and a few other publicly available | | attorneys representing plaintiffs \$600 an hour for |
| 1 | information. | | your time; is that correct? |
| 17 | Q. Are those materials contained in the | 17 | A. That's correct. |
| | two notebooks sitting in front of you? | 18 | Q. Do you charge a different rate for |
| 19 | A. Yes. | | testimony versus your review of materials? |
| 20 | MR. HEGARTY: I will designate | 20 | A. No. I've never been I've never |
| 21 | those two notebooks as Exhibit Number 1. | | had to testify. So, but as of right now, no, I |
| 22 23 | (2 Notebooks marked for identification as Harlow Exhibit 1) | | have not. |
| 143 | identification as Harlow Exhibit 1.) | 23 | Q. What did you base the \$600 an hour |
| | BY MR. HEGARTY: | 2/ | figure on? In other words, where did you come up |

| D 10 | Press 20 |
|--|---|
| Page 18 1 with that number? | Page 20 1 have been provided for you. |
| 2 A. Through colleagues of mine who are | 2 (Document marked for |
| 3 attorneys, and I asked what was an appropriate | 3 identification as Harlow Exhibit 2.) |
| 4 amount. | 4 MR. TISI: I assume this is |
| 5 Q. What's a who's a colleague of | 5 Exhibit 2? |
| 6 yours that's an attorney that you had that | 6 MR. HEGARTY: Yes. As I said, |
| 7 discussion with? | 7 I'm marking that as Exhibit Number 2. |
| 8 MR. TISI: Well, let me object | 8 MR. TISI: Okay. I'm sorry. |
| 9 to the extent he was asking any advice | 9 BY MR. HEGARTY: |
| from from other lawyers about about | 10 Q. Please look at Exhibit Number 2, |
| what he should charge. | 11 Dr. Harlow, and tell us whether those are the |
| 12 You can give a general a | 12 invoices that you have issued in connection with |
| 13 general idea. | 13 your work in this case. |
| 14 MR. HEGARTY: All I'm asking | 14 A. Well, these are these are copies |
| 15 for is a name. | 15 of the same invoice. |
| 16 MR. TISI: Yeah, I understand. | 16 Q. There are three separate invoices, |
| 17 THE WITNESS: His name is | 17 correct? |
| 18 Robert Adelman. He's an attorney in | 18 A. No. These all appear to be the same |
| 19 Connecticut. | 19 invoice. |
| 20 BY MR. HEGARTY: | |
| | MR. TISI: Let me see. Maybe they collated them differently. |
| 21 Q. And with regard to this this \$600 22 an hour figure, you don't make that much as a | 22 I think I think I know what |
| 23 professor at Boston University, do you? | |
| 23 professor at Boston University, do you? 24 A. No. | 11 3 0 |
| | • |
| Page 19 1 Q. Did you receive a retainer in | Page 21 MR. HEGARTY: Okay. |
| 2 connection with your work in this litigation? | 2 MR. TISI: I think they |
| 3 A. No. | 3 printed them. |
| 4 Q. Have you invoiced to the lawyers | 4 MR. HEGARTY: So do you have 1 |
| 5 representing plaintiffs the time that you have | 5 as well in your group? |
| 6 spent working on this litigation? | 6 MR. TISI: I think you |
| 7 A. Yes. | 7 probably. I have |
| 8 Q. Do you invoice as well expenses that | 8 BY MR. HEGARTY: |
| 9 you've incurred associated with your work on thi | |
| 10 litigation? | 10 A. 2, 3. We're missing 1. |
| 11 A. Yes. | 11 MR. HEGARTY: Okay. Let's go |
| 12 Q. For example, you flew down here from | • |
| 13 Boston, correct? | 13 (Recess: 9:34 a.m |
| 14 A. Yes. | 14 9:36 a.m.) |
| 15 Q. Did you fly first class? | 15 BY MR. HEGARTY: |
| 16 A. No. | 16 Q. Does Boston University have |
| 17 Q. Do you intend to invoice the cost of | 17 disclosure policies for consulting outside of your |
| 18 that flight to the attorneys representing | 18 work at the university? |
| 19 plaintiffs in this case? | 19 A. I believe it's only if it exceeds a |
| 1 - | 20 certain amount. |
| 1/U A 188 | |
| | 21 () Have you disclosed the work you are |
| 21 Just looking for my water. | 21 Q. Have you disclosed the work you are |
| Just looking for my water. MR. TISI: I'll get it. | 22 doing in this litigation pursuant to any |
| 21 Just looking for my water. | · · · · · · · · · · · · · · · · · · · |

Page 22

- 1 Q. You have not filled out any type of
- 2 form disclosing that you're -- you have consulted
- 3 with and are a designated expert witness for
- 4 plaintiffs in this litigation?
- 5 A. Not at this point. We do that at
- 6 the end of the year. So if they ask about events
- 7 that happened in the past year, I will evaluate.
- 8 I look will look at the form that they provide and
- 9 complete it accordingly.
- 10 Q. You started working with the
- 11 attorneys representing the plaintiffs in this case
- 12 back in 2023, correct?
- 13 A. Yes.
- 14 Q. Did you prepare any type of
- 15 disclosure form for Boston University at the end
- 16 of 2023?
- 17 A. No, I did not.
- 18 Q. You needed to do so, didn't you?
- 19 A. I would have to check on that.
- 20 Q. I've looked at the policies online,
- 21 and from my review, it appears that you would need
- 22 to fill out a disclosure form for your work on
- 23 this case.
- Is that not your understanding?

Page 23

- 1 A. I will check on that when I get
- 2 back.
- 3 Q. Have you orally or in any other type
- 4 of writing advised anyone at Boston University
- 5 about your work on this case?
- 6 A. Only Dr. Rothman, who I had done 7 work with.
- 8 Q. Other than Dr. Rothman, did you
- 9 advise anyone else at Boston University about your
- 10 work on this litigation?
- 11 A. No.
- 12 Q. What do you consider your occupation
- 13 to be?
- 14 A. A professor of epidemiology.
- 15 Q. What is your current area of
- 16 expertise in epidemiology?
- 17 A. Women's reproductive and gynecologic
- 18 health.
- 19 Q. Is there a particular subtype of
- 20 those two categories that you're focused on
- 21 currently?
- 22 A. I'm currently focusing on benign
- 23 gynecologic disorders.
- Q. Are you currently involved in any

ge 22

1 research activities at Boston University?

- 2 A. Yes.
- Q. What is the focus of your research
- 4 currently?
- 5 A. I'm currently studying unexplained
- 6 vulvar pain. I'm also studying the impact of --
- 7 of factors that influence women's urological
- 8 health.
- 9 Q. What percentage of your work time do
- 10 you devote to this research?
- 11 A. This year, about 50 percent.
 - Q. Are you currently teaching students?
- 13 A. This year, yes, I taught a class. I
- 14 taught.

12

- 15 Q. What class did you teach this year?
- 16 A. This year I taught Guided
- 17 Epidemiology Research.
- 18 Q. Have you always taught classes while
- 19 you've been at Boston University?
- 20 A. Yes.
- Q. Besides teaching and research, what
- 22 other activities do you do at Boston University
- 23 work-wise?
- A. I sit on the -- I sit on committees.

Page 25

Page 24

- 1 I have -- I currently sit on the appointment and
- 2 promotions committee for the -- for the school.
- 3 directed the master's of public health -- I
- 4 codirected the master's of public health program
- 5 in epidemiology and biostatistics. Those are the
- 6 most recent.
- 7 Q. What percentage of your work time do
- 8 you spend on committees?
- 9 A. 10 percent.
- 10 Q. You told me that 50 percent goes to
- 11 research, 10 percent to committees.
- 12 Is then 40 percent devoted to
- 13 teaching?
- 14 A. About that, yes.
- 15 Q. Are you affiliated in any way still
- 16 with the University of Minnesota?
- 17 A. I have an adjunct appointment, that
- 18 my work on women's urological condition is a
- 19 subcontract through the University of Minnesota.
- 20 And as you know from my CV, I chaired the
- 21 Department of Epidemiology there for 10 years.
- Q. How many hours a week do you
- 23 typically put in at Boston University?
- A. Well, how many hours I put in?

| | | Page 26 | | Page 28 |
|--|---|---|--|---|
| 1 | Probably 40 to 50. (Laugh). | | case or c | ases involving talcum powder use and |
| 2 | Q. Okay. Have you taught courses a | | ovarian o | |
| 3 | | 3 | | Yeah. I did provide consultation on |
| 4 | A. No. | | | of acetaminophen use in pregnant women and |
| 5 | Q. You don't teach gynecologic | I . | | iation with neurodevelopmental disorders. |
| 6 | oncologists, correct? | 1 | | That |
| 7 | A. No. | 7 | _ | I was not an expert. |
| 8 | Q. You don't teach oncologists, | 8 | 3 Q. | That consultation has been |
| 9 | correct? | Ģ | publicize | ed in the press and on the internet, |
| 10 | A. No. | 10 | correct? | |
| 11 | Q. Prior to this case, have you ever | 11 | Α. | That is correct. |
| 12 | been, to your knowledge, designated as an e | expert 12 | Q. | In fact, there is an article that |
| 13 | witness in a legal proceeding? | 13 | reports the | hat you serve on a lawyer-sponsored |
| 14 | A. No. | 14 | Autism J | Justice's team of experts? |
| 15 | Q. What percentage of your work tir | ne in 15 | A. | I had, correct. I don't know if I'm |
| 16 | 2023 was spent on litigation matters? | 16 | still invo | lved. |
| 17 | A. 10 percent, maybe less. | 17 | Q. | That team includes Erin Brockovich, |
| 18 | Q. What percentage of your work tir | ne in 18 | 3 correct? | |
| 19 | 2024 has been spent on litigation matters? | 19 | Α. | That is correct. |
| 20 | A. About the same. | 20 | Q. | And with regard to that |
| 21 | Q. In 2023, what percentage of your | 21 | consulta | tion, again, those are that |
| 22 | total income was from work on litigation m | atters? 22 | consulta | tion has been related to claims that |
| 23 | A. I would say less than 10 percent. | 23 | acetamir | nophen use during pregnancy causes autism? |
| 24 | Q. Are you consulting with regard to | 24 | Α. | Correct. |
| | | Page 27 | | D 20 |
| | | 1 age 27 | | Page 29 |
| 1 | litigation on any matters other than mat | · | Q. | Also that acetaminophen use during |
| | litigation on any matters other than mat involving talcum powder and ovarian c | ters 1 | - | |
| | involving talcum powder and ovarian c A. Currently, no. | ters 1 ancer? 2 | 2 pregnano | Also that acetaminophen use during |
| 2 | involving talcum powder and ovarian c A. Currently, no. Q. Have you ever consulted on a | ters 1 ancer? 2 any 2 | pregnand A. | Also that acetaminophen use during cy causes ADHD; is that correct? It's the entire spectrum of velopmental disorders. |
| 2 3 4 5 | involving talcum powder and ovarian c A. Currently, no. Q. Have you ever consulted on a litigation matters besides cases involving | ters 1 ancer? 2 any 2 ang talcum 5 | pregnand A. neurodes Q. | Also that acetaminophen use during by causes ADHD; is that correct? It's the entire spectrum of welopmental disorders. Have you been paid anything for your |
| 2 3 4 5 6 | involving talcum powder and ovarian c A. Currently, no. Q. Have you ever consulted on a litigation matters besides cases involving powder use and claims of ovarian cancer. | ters 1 ancer? 2 any 2 ang talcum 5 er? 6 | pregnand A. neurodev Q. consulta | Also that acetaminophen use during by causes ADHD; is that correct? It's the entire spectrum of welopmental disorders. Have you been paid anything for your tion work as to that subject area? |
| 2 3 4 5 6 7 | involving talcum powder and ovarian c A. Currently, no. Q. Have you ever consulted on a litigation matters besides cases involvir powder use and claims of ovarian cance A. Could you just repeat that, ple | ters 1 ancer? 2 any 4 ang talcum 5 er? 6 ease? 7 | pregnand A. neurodev C. consultar A. | Also that acetaminophen use during by causes ADHD; is that correct? It's the entire spectrum of welopmental disorders. Have you been paid anything for your tion work as to that subject area? Yes. |
| 2 3 4 5 6 7 8 | involving talcum powder and ovarian c A. Currently, no. Q. Have you ever consulted on a litigation matters besides cases involving powder use and claims of ovarian cancer. A. Could you just repeat that, play Q. Sure. | ters 1 ancer? 2 any 2 ang talcum 5 ease? 3 | 2 pregnand 3 A. 4 neurodev 5 Q. 5 consulta 7 A. 8 Q. | Also that acetaminophen use during by causes ADHD; is that correct? It's the entire spectrum of welopmental disorders. Have you been paid anything for your tion work as to that subject area? Yes. How much have you been paid? |
| 2 3 4 5 6 7 8 9 | involving talcum powder and ovarian c A. Currently, no. Q. Have you ever consulted on a litigation matters besides cases involving powder use and claims of ovarian cance A. Could you just repeat that, ple Q. Sure. Have you ever consulted on a | ters 1 ancer? 2 any 2 any 4 ang talcum 5 ease? 6 | Pregnand A. neurodev C. Q. Consultar A. A. Q. A. | Also that acetaminophen use during by causes ADHD; is that correct? It's the entire spectrum of evelopmental disorders. Have you been paid anything for your tion work as to that subject area? Yes. How much have you been paid? I would have to to go back, but |
| 2 3 4 5 6 7 8 9 | involving talcum powder and ovarian c A. Currently, no. Q. Have you ever consulted on a litigation matters besides cases involvir powder use and claims of ovarian cance A. Could you just repeat that, ple Q. Sure. Have you ever consulted on a litigation matter other than in cases invo | ters 1 ancer? 2 any 4 ang talcum 5 ease? 6 solving 10 | pregnand A. neurodev Q. consulta A. Q. A. Q. A. D. it was | Also that acetaminophen use during by causes ADHD; is that correct? It's the entire spectrum of welopmental disorders. Have you been paid anything for your tion work as to that subject area? Yes. How much have you been paid? I would have to to go back, but I would be surprised if it was more than |
| 2 3 4 5 6 7 8 9 10 | involving talcum powder and ovarian c A. Currently, no. Q. Have you ever consulted on a litigation matters besides cases involvir powder use and claims of ovarian cance A. Could you just repeat that, ple Q. Sure. Have you ever consulted on a litigation matter other than in cases involving talcum powder use and ovarian cancer of | ters 1 ancer? 2 any 2 any 4 ang talcum 5 ease? 6 solving 10 claims? 11 | 2 pregnand 3 A. 4 neurodev 5 Q. 5 consultar 7 A. 8 Q. 9 A. 9 it was \$5,000. | Also that acetaminophen use during by causes ADHD; is that correct? It's the entire spectrum of evelopmental disorders. Have you been paid anything for your tion work as to that subject area? Yes. How much have you been paid? I would have to to go back, but I would be surprised if it was more than It may have been less. I just I don't |
| 2 3 4 5 6 7 8 9 10 11 12 | involving talcum powder and ovarian c A. Currently, no. Q. Have you ever consulted on a litigation matters besides cases involving powder use and claims of ovarian cancer A. Could you just repeat that, ple Q. Sure. Have you ever consulted on a litigation matter other than in cases involving talcum powder use and ovarian cancer of MR. TISI: And the answer | ters ancer? 2 ancer? 2 any 2 any 2 ang talcum 5 ease? 6 colving 10 claims? 11 is 12 | 2 pregnand 3 A. neurodev 5 Q. consultar 7 A. B. Q. Q. A. D. it was \$5,000. | Also that acetaminophen use during by causes ADHD; is that correct? It's the entire spectrum of evelopmental disorders. Have you been paid anything for your tion work as to that subject area? Yes. How much have you been paid? I would have to to go back, but I would be surprised if it was more than It may have been less. I just I don't ter. |
| 2 3 4 5 6 7 8 9 10 11 12 13 | involving talcum powder and ovarian c A. Currently, no. Q. Have you ever consulted on a litigation matters besides cases involvir powder use and claims of ovarian cance A. Could you just repeat that, ple Q. Sure. Have you ever consulted on a litigation matter other than in cases involving talcum powder use and ovarian cancer of MR. TISI: And the answer yes or no, just to be clear. He's not | ters 1 ancer? 2 any 2 any 5 any 6 ease? 6 olving 10 claims? 11 is 12 | pregnand A. neurodev Q. consulta A. Q. Q. A. Dit was \$5,000. | Also that acetaminophen use during by causes ADHD; is that correct? It's the entire spectrum of evelopmental disorders. Have you been paid anything for your tion work as to that subject area? Yes. How much have you been paid? I would have to to go back, but I would be surprised if it was more than It may have been less. I just I don't ter. Is that consultation work still |
| 2 3 4 5 6 7 8 9 10 11 12 13 14 | involving talcum powder and ovarian c A. Currently, no. Q. Have you ever consulted on a litigation matters besides cases involvir powder use and claims of ovarian cance A. Could you just repeat that, ple Q. Sure. Have you ever consulted on a litigation matter other than in cases involving the consulted on a litigation matter other than in cases involving the consulted on a litigation matter other than in cases involving the consulted on a litigation matter other than in cases involving the consulted on a litigation matter other than in cases involving the consulted on a litigation matter other than in cases involving the consulted on a litigation matter other than in cases involving the consulted on a litigation matter other than in cases involving the consulted on a litigation matter other than in cases involving the consulted on a litigation matter other than in cases involving the consulted on a litigation matter other than in cases involving the consulted on a litigation matter other than in cases involving the consulted on a litigation matter other than in cases involving the consulted on a litigation matter other than in cases involving the consulted on a litigation matter other than in cases involving the consulted on a litigation matter other than in cases involving the consulted on a litigation matter other than in cases involving the consulted on a litigation matter other than in cases involving the consulted on a litigation matter other than in cases involving the consulted on a litigation matter other than in cases involving the consulted on a litigation matter other than in cases involving the consulted on a litigation matter other than in cases involving the consulted on a litigation matter other than in cases involving the consulted on a litigation matter other than in cases involving the consulted on a litigation matter other than in cases involving the consulted on a litigation matter other than in cases involving the consulted on a litigation matter other than in cases involving the consulted | ters 1 ancer? 2 any 2 any 4 ang talcum 5 ease? 6 solving 10 claims? 11 is 12 her you 14 | Pregnand A. neurodev Q. consulta A. Q. A. it was \$5,000. Premember Q. ongoing | Also that acetaminophen use during by causes ADHD; is that correct? It's the entire spectrum of welopmental disorders. Have you been paid anything for your tion work as to that subject area? Yes. How much have you been paid? I would have to to go back, but I would be surprised if it was more than It may have been less. I just I don't ter. Is that consultation work still? |
| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 | involving talcum powder and ovarian c A. Currently, no. Q. Have you ever consulted on a litigation matters besides cases involving powder use and claims of ovarian cancer A. Could you just repeat that, ple Q. Sure. Have you ever consulted on a litigation matter other than in cases involving talcum powder use and ovarian cancer of MR. TISI: And the answer yes or no, just to be clear. He's not asking you what you did, just whet did. | ters 1 2 2 3 3 3 4 4 4 4 4 4 4 | 2 pregnand 3 A. neurodev 5 Q. consultar 7 A. Q. Q. A. it was \$5,000. 2 remember Q. ongoing A. | Also that acetaminophen use during by causes ADHD; is that correct? It's the entire spectrum of evelopmental disorders. Have you been paid anything for your stion work as to that subject area? Yes. How much have you been paid? I would have to to go back, but I would be surprised if it was more than It may have been less. I just I don't ter. Is that consultation work still? Not that I'm aware of. |
| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 | involving talcum powder and ovarian c A. Currently, no. Q. Have you ever consulted on a litigation matters besides cases involvir powder use and claims of ovarian cance A. Could you just repeat that, ple Q. Sure. Have you ever consulted on a litigation matter other than in cases involving talcum powder use and ovarian cancer of MR. TISI: And the answer yes or no, just to be clear. He's not asking you what you did, just whet did. MR. HEGARTY: That's rig | ters 1 | 2 pregnand 3 A. neurodev 5 Q. consultar 7 A. Q. Q. d. it was \$5,000. remember Q. congoing 6 A. Q. Q. | Also that acetaminophen use during by causes ADHD; is that correct? It's the entire spectrum of evelopmental disorders. Have you been paid anything for your tion work as to that subject area? Yes. How much have you been paid? I would have to to go back, but I would be surprised if it was more than lit may have been less. I just I don't ter. Is that consultation work still? Not that I'm aware of. When did you last, as you understand |
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| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 | involving talcum powder and ovarian c A. Currently, no. Q. Have you ever consulted on a litigation matters besides cases involvir powder use and claims of ovarian cance A. Could you just repeat that, ple Q. Sure. Have you ever consulted on a litigation matter other than in cases involved and the consulted on a litigation matter other than in cases involved asking powder use and ovarian cancer of the county of the clear. He's not asking you what you did, just whet did. MR. HEGARTY: That's right THE WITNESS: I'm not so what "litigation matter" means. If yould define that for me? BY MR. HEGARTY: | ters 1 | 2 pregnand 3 A. 4 neurodev 5 Q. 5 consulta 7 A. 8 Q. 9 A. 10 it was 10 \$5,000. 11 remember 12 Q. 13 ongoing 15 A. 16 Q. 17 it serve, 18 litigation 18 A. 19 prior to 1 | Also that acetaminophen use during by causes ADHD; is that correct? It's the entire spectrum of velopmental disorders. Have you been paid anything for your tion work as to that subject area? Yes. How much have you been paid? I would have to to go back, but I would be surprised if it was more than It may have been less. I just I don't ter. Is that consultation work still? Not that I'm aware of. When did you last, as you understand as a consult as a consultant in that a in that subject area? |
| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 | involving talcum powder and ovarian c A. Currently, no. Q. Have you ever consulted on a litigation matters besides cases involvir powder use and claims of ovarian cance A. Could you just repeat that, ple Q. Sure. Have you ever consulted on a litigation matter other than in cases invetalcum powder use and ovarian cancer of MR. TISI: And the answer yes or no, just to be clear. He's not asking you what you did, just whet did. MR. HEGARTY: That's rig THE WITNESS: I'm not so what "litigation matter" means. If could define that for me? BY MR. HEGARTY: Q. Sure. | ters 1 2 2 3 3 3 3 3 3 3 3 | Pregnand A. Ineurodev Q. Consulta A. R. Q. A. It was \$5,000. Premembe Q. It serve, R. Itigation A. Prior to 1 2023. | Also that acetaminophen use during by causes ADHD; is that correct? It's the entire spectrum of velopmental disorders. Have you been paid anything for your tion work as to that subject area? Yes. How much have you been paid? I would have to to go back, but I would be surprised if it was more than It may have been less. I just I don't ter. Is that consultation work still? Not that I'm aware of. When did you last, as you understand as a consult as a consultant in that a in that subject area? Probably I would think earlier, my work on this, in I believe it was |
| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 | involving talcum powder and ovarian c A. Currently, no. Q. Have you ever consulted on a litigation matters besides cases involving powder use and claims of ovarian cancer. A. Could you just repeat that, plet Q. Sure. Have you ever consulted on a litigation matter other than in cases involving talcum powder use and ovarian cancer of MR. TISI: And the answer yes or no, just to be clear. He's not asking you what you did, just whet did. MR. HEGARTY: That's right THE WITNESS: I'm not so what "litigation matter" means. If yould define that for me? BY MR. HEGARTY: Q. Sure. Have you ever consulted on with the could define that for me? | ters 1 | 2 pregnand 3 A. neurodev 4 Q. consultar 5 Q. do A. it was \$5,000. remember Q. ongoing A. Q. it serve, B. litigation A. prior to a 2023. Q. Q. | Also that acetaminophen use during by causes ADHD; is that correct? It's the entire spectrum of velopmental disorders. Have you been paid anything for your tion work as to that subject area? Yes. How much have you been paid? I would have to to go back, but I would be surprised if it was more than It may have been less. I just I don't ter. Is that consultation work still? Not that I'm aware of. When did you last, as you understand as a consult as a consultant in that a in that subject area? Probably I would think earlier, my work on this, in I believe it was Is it your opinion that |
| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 | involving talcum powder and ovarian c A. Currently, no. Q. Have you ever consulted on a litigation matters besides cases involvir powder use and claims of ovarian cance A. Could you just repeat that, ple Q. Sure. Have you ever consulted on a litigation matter other than in cases invetalcum powder use and ovarian cancer of MR. TISI: And the answer yes or no, just to be clear. He's not asking you what you did, just whet did. MR. HEGARTY: That's rig THE WITNESS: I'm not so what "litigation matter" means. If could define that for me? BY MR. HEGARTY: Q. Sure. | ters 1 | 2 pregnand 3 A. 4 neurodev 5 Q. 5 consulta 6 A. 8 Q. 9 A. 9 it was 9 \$5,000. 7 remember 8 Q. 9 ongoing 9 A. 10 it serve, 11 it serve, 12 litigation 12 A. 12 Q. 13 acetamir | Also that acetaminophen use during by causes ADHD; is that correct? It's the entire spectrum of velopmental disorders. Have you been paid anything for your tion work as to that subject area? Yes. How much have you been paid? I would have to to go back, but I would be surprised if it was more than It may have been less. I just I don't ter. Is that consultation work still? Not that I'm aware of. When did you last, as you understand as a consult as a consultant in that a in that subject area? Probably I would think earlier, my work on this, in I believe it was |

| | Page 30 | | Page 32 |
|----|--|----|---|
| 1 | Objection to the extent to which you | 1 | A. Yes. |
| 2 | develop that in the course of your | 2 | Q. What was the relative risk or odds |
| 3 | consultation. He can ask you about your | 3 | ratio that you came up came away with from your |
| 4 | published work, but but anything you | 4 | review of that literature? |
| 5 | developed in the course of your | 5 | MR. TISI: Again, I'm going to |
| 6 | consultation with those attorneys, I | 6 | instruct you if you developed that |
| 7 | instruct you not to answer. | 7 | THE WITNESS: I just |
| 8 | MR. HEGARTY: Wait. Let me | 8 | MR. TISI: Wait. Let me |
| 9 | clarify. I'm asking him without regard | 9 | finish. |
| 10 | to consultation. | 10 | If you developed that in the |
| 11 | MR. TISI: If you develop | 11 | context of your consultation with lawyers |
| | BY MR. HEGARTY: | 12 | to advise lawyers about pending |
| 13 | | 13 | |
| 14 | Q. Is it your opinion? | | litigation in legal matters, then I |
| | MR. TISI: If you develop that | 14 | instruct you not to answer that question. |
| 15 | opinion in connection with your | 15 | If you did it otherwise, then feel free |
| 16 | consultation work, I instruct you not to | 16 | to answer the question. |
| 17 | answer that question. | 17 | THE WITNESS: I did not. |
| 1 | BY MR. HEGARTY: | 18 | I'm sorry. Repeat the |
| 19 | Q. Are you going to follow Mr. Tisi's | 19 | question, please. |
| 1 | instructions? | | BY MR. HEGARTY: |
| 21 | A. Yes. | 21 | Q. Sure. |
| 22 | MR. HEGARTY: What's the basis | 22 | Did you develop an opinion as to the |
| 23 | of that objection? | | odds ratio of relative risk of neurologic |
| 24 | MR. TISI: He developed he | 24 | disorders, including autism, from acetaminophen |
| | Page 31 | | Page 33 |
| 1 | developed an opinion. Unless he | 1 | use during pregnancy? |
| 2 | expressed it publicly. Okay? You can | 2 | A. I did not develop an opinion. I |
| 3 | ask him about his public statements, but | 1 | reviewed the literature as to what had been |
| 4 | if he expressed it if he developed an | | published. |
| 5 | opinion and he expressed it to lawyers, | 5 | Q. Did you come away with an opinion as |
| 6 | he developed it during consultation. | 6 | to whether the studies showed a dose response? |
| 7 | And if you if you disagree | 7 | A. I don't recall. |
| 8 | with me, I'm more than happy | 8 | Q. Did you look at any animal studies |
| 9 | MR. HEGARTY: That's all | | related to acetaminophen use during pregnancy and |
| 10 | right. We're not I do disagree with | 10 | autism or neurologic disorders? |
| 11 | you, but we're not going to be it's | 11 | A. I looked at biological, yes. Yes. |
| 12 | not going to be resolved here. | 12 | Q. You looked at biologic plausibility |
| 13 | MR. TISI: Okay. | 13 | |
| 14 | BY MR. HEGARTY: | 14 | A. Yes. |
| 15 | Q. Have you ever made any public | 15 | Q. Those included animal studies? |
| 16 | statement that acetaminophen use during pregnancy | 16 | A. Again, I don't recall. I would have |
| 17 | causes autism or any other neurologic disorder? | 17 | to go back. |
| 18 | A. I made a public statement that there | 18 | Q. Do you remember if you looked at any |
| 19 | was evidence of an association. I do not believe | 19 | cell studies? |
| 20 | I ever used the word "cause." | 20 | A. I don't recall. |
| 21 | Q. Did you make the statement that | 21 | Q. Did you compare competing |
| 22 | there was evidence of an association based on your | 22 | explanations for any positive increase in risk |
| | review of all the epidemiologic studies looking at | | from acetaminophen use during pregnancy and |
| | acetaminophen use and neurologic disorders? | | autism? |
| 23 | review of all the epidemiologic studies looking at | 23 | from acetaminophen use during pregnancy and |

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|---|--|
| 1 A. Absolutely. That is the way in | 1 Q. Have you ever served on an FDA |
| 2 which I usually evaluate scientific literature. | 2 committee? |
| 3 Q. Did those competing risks include | 3 A. Only the conference that was held in |
| 4 genetics or just leave it at that. | 4 1994, I believe, that was sponsored by the FDA. I |
| 5 A. I don't recall. | 5 was an invited participant. |
| 6 MR. TISI: I don't want to | 6 Q. And we'll talk about that here in a |
| 7 interrupt you, but it looks like we're on | 7 moment. |
| 8 mute and for some reason Tracy can't hear | 8 A. Yeah. |
| 9 us. | 9 Q. Other than that, other than your |
| 10 MR. HEGARTY: Okay. Let's go | 10 participation in that 1994 FDA workshop |
| off the record. | 11 A. Yes. |
| MS. FINKEN: No, I can hear. | 12 Q have you ever otherwise served on |
| MR. TISI: You can hear now? | 13 any FDA committee or been otherwise involved in |
| 14 MS. FINKEN: Yes. | 14 FDA with regard to a cosmetic including talcum |
| MR. TISI: Okay. Sorry. | 15 powder? |
| 16 BY MR. HEGARTY: | 16 A. Yeah. No. |
| 17 Q. Sounds like from your last response | 17 Q. FDA has never contacted you about |
| 18 you applied the same methodology in looking at the | 18 talcum powder, correct? |
| 19 epidemiologic studies on acetaminophen use during | 19 A. No. |
| 20 pregnancy and autism as you did for this case? | 20 Q. You have never worked for Health |
| 21 A. That's correct. | 21 Canada, correct? |
| 22 Q. Have you ever been hired by a | 22 A. Correct. |
| 23 company to consult regarding a cosmetic product? | 23 Q. You have never worked for any |
| 24 A. No. | 24 foreign regulatory agency, correct? |
| Page 35 | |
| | Page 37 |
| _ | |
| 1 Q. Has any cosmetic pharmaceutical or | 1 A. Correct. |
| 1 Q. Has any cosmetic pharmaceutical or 2 chemical company ever hired you as a consultant on | 1 A. Correct. 2 Q. You have never communicated with |
| 1 Q. Has any cosmetic pharmaceutical or 2 chemical company ever hired you as a consultant on 3 any matter? | 1 A. Correct. 2 Q. You have never communicated with 3 Health Canada? |
| 1 Q. Has any cosmetic pharmaceutical or 2 chemical company ever hired you as a consultant on 3 any matter? 4 A. No. | 1 A. Correct. 2 Q. You have never communicated with 3 Health Canada? 4 A. Correct. |
| Q. Has any cosmetic pharmaceutical or chemical company ever hired you as a consultant on any matter? A. No. Q. Have you ever been employed by a | 1 A. Correct. 2 Q. You have never communicated with 3 Health Canada? 4 A. Correct. 5 Q. Have you ever referenced in any |
| Q. Has any cosmetic pharmaceutical or chemical company ever hired you as a consultant on any matter? A. No. Q. Have you ever been employed by a pharmaceutical medical device consumer product or | A. Correct. Q. You have never communicated with Health Canada? A. Correct. Q. Have you ever referenced in any publication of yours a finding by Health Canada? |
| Q. Has any cosmetic pharmaceutical or chemical company ever hired you as a consultant on any matter? A. No. Q. Have you ever been employed by a pharmaceutical medical device consumer product or chemical company in any capacity? | A. Correct. Q. You have never communicated with Health Canada? A. Correct. Q. Have you ever referenced in any publication of yours a finding by Health Canada? A. No. |
| 1 Q. Has any cosmetic pharmaceutical or 2 chemical company ever hired you as a consultant on 3 any matter? 4 A. No. 5 Q. Have you ever been employed by a 6 pharmaceutical medical device consumer product or 7 chemical company in any capacity? 8 A. No. | A. Correct. Q. You have never communicated with Health Canada? A. Correct. Q. Have you ever referenced in any publication of yours a finding by Health Canada? A. No. Q. Have you ever referenced in any |
| 1 Q. Has any cosmetic pharmaceutical or 2 chemical company ever hired you as a consultant on 3 any matter? 4 A. No. 5 Q. Have you ever been employed by a 6 pharmaceutical medical device consumer product or 7 chemical company in any capacity? 8 A. No. 9 Q. Have you ever been involved in a | 1 A. Correct. 2 Q. You have never communicated with 3 Health Canada? 4 A. Correct. 5 Q. Have you ever referenced in any 6 publication of yours a finding by Health Canada? 7 A. No. 8 Q. Have you ever referenced in any 9 publication of yours a Health Canada risk |
| 1 Q. Has any cosmetic pharmaceutical or 2 chemical company ever hired you as a consultant on 3 any matter? 4 A. No. 5 Q. Have you ever been employed by a 6 pharmaceutical medical device consumer product or 7 chemical company in any capacity? 8 A. No. 9 Q. Have you ever been involved in a 10 company's analysis of safety data regarding a | 1 A. Correct. 2 Q. You have never communicated with 3 Health Canada? 4 A. Correct. 5 Q. Have you ever referenced in any 6 publication of yours a finding by Health Canada? 7 A. No. 8 Q. Have you ever referenced in any 9 publication of yours a Health Canada risk 10 assessment? |
| 1 Q. Has any cosmetic pharmaceutical or 2 chemical company ever hired you as a consultant on 3 any matter? 4 A. No. 5 Q. Have you ever been employed by a 6 pharmaceutical medical device consumer product or 7 chemical company in any capacity? 8 A. No. 9 Q. Have you ever been involved in a 10 company's analysis of safety data regarding a 11 cosmetic? | 1 A. Correct. 2 Q. You have never communicated with 3 Health Canada? 4 A. Correct. 5 Q. Have you ever referenced in any 6 publication of yours a finding by Health Canada? 7 A. No. 8 Q. Have you ever referenced in any 9 publication of yours a Health Canada risk 10 assessment? 11 A. Only the report that I currently |
| 1 Q. Has any cosmetic pharmaceutical or 2 chemical company ever hired you as a consultant on 3 any matter? 4 A. No. 5 Q. Have you ever been employed by a 6 pharmaceutical medical device consumer product or 7 chemical company in any capacity? 8 A. No. 9 Q. Have you ever been involved in a 10 company's analysis of safety data regarding a 11 cosmetic? 12 A. No. | 1 A. Correct. 2 Q. You have never communicated with 3 Health Canada? 4 A. Correct. 5 Q. Have you ever referenced in any 6 publication of yours a finding by Health Canada? 7 A. No. 8 Q. Have you ever referenced in any 9 publication of yours a Health Canada risk 10 assessment? 11 A. Only the report that I currently 12 wrote. |
| 1 Q. Has any cosmetic pharmaceutical or 2 chemical company ever hired you as a consultant on 3 any matter? 4 A. No. 5 Q. Have you ever been employed by a 6 pharmaceutical medical device consumer product or 7 chemical company in any capacity? 8 A. No. 9 Q. Have you ever been involved in a 10 company's analysis of safety data regarding a 11 cosmetic? 12 A. No. 13 Q. You have never worked for FDA, | 1 A. Correct. 2 Q. You have never communicated with 3 Health Canada? 4 A. Correct. 5 Q. Have you ever referenced in any 6 publication of yours a finding by Health Canada? 7 A. No. 8 Q. Have you ever referenced in any 9 publication of yours a Health Canada risk 10 assessment? 11 A. Only the report that I currently 12 wrote. 13 Q. My question was specifically as to a |
| 1 Q. Has any cosmetic pharmaceutical or 2 chemical company ever hired you as a consultant on 3 any matter? 4 A. No. 5 Q. Have you ever been employed by a 6 pharmaceutical medical device consumer product or 7 chemical company in any capacity? 8 A. No. 9 Q. Have you ever been involved in a 10 company's analysis of safety data regarding a 11 cosmetic? 12 A. No. 13 Q. You have never worked for FDA, 14 correct? | 1 A. Correct. 2 Q. You have never communicated with 3 Health Canada? 4 A. Correct. 5 Q. Have you ever referenced in any 6 publication of yours a finding by Health Canada? 7 A. No. 8 Q. Have you ever referenced in any 9 publication of yours a Health Canada risk 10 assessment? 11 A. Only the report that I currently 12 wrote. 13 Q. My question was specifically as to a 14 publication. |
| 1 Q. Has any cosmetic pharmaceutical or 2 chemical company ever hired you as a consultant on 3 any matter? 4 A. No. 5 Q. Have you ever been employed by a 6 pharmaceutical medical device consumer product or 7 chemical company in any capacity? 8 A. No. 9 Q. Have you ever been involved in a 10 company's analysis of safety data regarding a 11 cosmetic? 12 A. No. 13 Q. You have never worked for FDA, 14 correct? 15 A. Correct. | 1 A. Correct. 2 Q. You have never communicated with 3 Health Canada? 4 A. Correct. 5 Q. Have you ever referenced in any 6 publication of yours a finding by Health Canada? 7 A. No. 8 Q. Have you ever referenced in any 9 publication of yours a Health Canada risk 10 assessment? 11 A. Only the report that I currently 12 wrote. 13 Q. My question was specifically as to a 14 publication. 15 Your report has not been published, |
| 1 Q. Has any cosmetic pharmaceutical or 2 chemical company ever hired you as a consultant on 3 any matter? 4 A. No. 5 Q. Have you ever been employed by a 6 pharmaceutical medical device consumer product or 7 chemical company in any capacity? 8 A. No. 9 Q. Have you ever been involved in a 10 company's analysis of safety data regarding a 11 cosmetic? 12 A. No. 13 Q. You have never worked for FDA, 14 correct? 15 A. Correct. 16 Q. Have you ever worked for any | 1 A. Correct. 2 Q. You have never communicated with 3 Health Canada? 4 A. Correct. 5 Q. Have you ever referenced in any 6 publication of yours a finding by Health Canada? 7 A. No. 8 Q. Have you ever referenced in any 9 publication of yours a Health Canada risk 10 assessment? 11 A. Only the report that I currently 12 wrote. 13 Q. My question was specifically as to a 14 publication. 15 Your report has not been published, 16 correct? |
| 1 Q. Has any cosmetic pharmaceutical or 2 chemical company ever hired you as a consultant on 3 any matter? 4 A. No. 5 Q. Have you ever been employed by a 6 pharmaceutical medical device consumer product or 7 chemical company in any capacity? 8 A. No. 9 Q. Have you ever been involved in a 10 company's analysis of safety data regarding a 11 cosmetic? 12 A. No. 13 Q. You have never worked for FDA, 14 correct? 15 A. Correct. 16 Q. Have you ever worked for any 17 governmental agency, that is, been employed by a | 1 A. Correct. 2 Q. You have never communicated with 3 Health Canada? 4 A. Correct. 5 Q. Have you ever referenced in any 6 publication of yours a finding by Health Canada? 7 A. No. 8 Q. Have you ever referenced in any 9 publication of yours a Health Canada risk 10 assessment? 11 A. Only the report that I currently 12 wrote. 13 Q. My question was specifically as to a 14 publication. 15 Your report has not been published, 16 correct? 17 A. Correct. |
| 1 Q. Has any cosmetic pharmaceutical or 2 chemical company ever hired you as a consultant on 3 any matter? 4 A. No. 5 Q. Have you ever been employed by a 6 pharmaceutical medical device consumer product or 7 chemical company in any capacity? 8 A. No. 9 Q. Have you ever been involved in a 10 company's analysis of safety data regarding a 11 cosmetic? 12 A. No. 13 Q. You have never worked for FDA, 14 correct? 15 A. Correct. 16 Q. Have you ever worked for any 17 governmental agency, that is, been employed by a 18 governmental agency? | 1 A. Correct. 2 Q. You have never communicated with 3 Health Canada? 4 A. Correct. 5 Q. Have you ever referenced in any 6 publication of yours a finding by Health Canada? 7 A. No. 8 Q. Have you ever referenced in any 9 publication of yours a Health Canada risk 10 assessment? 11 A. Only the report that I currently 12 wrote. 13 Q. My question was specifically as to a 14 publication. 15 Your report has not been published, 16 correct? 17 A. Correct. 18 Q. So have you ever referenced in any |
| 1 Q. Has any cosmetic pharmaceutical or 2 chemical company ever hired you as a consultant on 3 any matter? 4 A. No. 5 Q. Have you ever been employed by a 6 pharmaceutical medical device consumer product or 7 chemical company in any capacity? 8 A. No. 9 Q. Have you ever been involved in a 10 company's analysis of safety data regarding a 11 cosmetic? 12 A. No. 13 Q. You have never worked for FDA, 14 correct? 15 A. Correct. 16 Q. Have you ever worked for any 17 governmental agency, that is, been employed by a 18 governmental agency? 19 A. Yes. Oh, employed by a government | 1 A. Correct. 2 Q. You have never communicated with 3 Health Canada? 4 A. Correct. 5 Q. Have you ever referenced in any 6 publication of yours a finding by Health Canada? 7 A. No. 8 Q. Have you ever referenced in any 9 publication of yours a Health Canada risk 10 assessment? 11 A. Only the report that I currently 12 wrote. 13 Q. My question was specifically as to a 14 publication. 15 Your report has not been published, 16 correct? 17 A. Correct. 18 Q. So have you ever referenced in any 19 publication of yours a Health Canada risk |
| 1 Q. Has any cosmetic pharmaceutical or 2 chemical company ever hired you as a consultant on 3 any matter? 4 A. No. 5 Q. Have you ever been employed by a 6 pharmaceutical medical device consumer product or 7 chemical company in any capacity? 8 A. No. 9 Q. Have you ever been involved in a 10 company's analysis of safety data regarding a 11 cosmetic? 12 A. No. 13 Q. You have never worked for FDA, 14 correct? 15 A. Correct. 16 Q. Have you ever worked for any 17 governmental agency, that is, been employed by a 18 governmental agency? 19 A. Yes. Oh, employed by a government 20 agency. No. | 1 A. Correct. 2 Q. You have never communicated with 3 Health Canada? 4 A. Correct. 5 Q. Have you ever referenced in any 6 publication of yours a finding by Health Canada? 7 A. No. 8 Q. Have you ever referenced in any 9 publication of yours a Health Canada risk 10 assessment? 11 A. Only the report that I currently 12 wrote. 13 Q. My question was specifically as to a 14 publication. 15 Your report has not been published, 16 correct? 17 A. Correct. 18 Q. So have you ever referenced in any 19 publication of yours a Health Canada risk 20 assessment? |
| 1 Q. Has any cosmetic pharmaceutical or 2 chemical company ever hired you as a consultant on 3 any matter? 4 A. No. 5 Q. Have you ever been employed by a 6 pharmaceutical medical device consumer product or 7 chemical company in any capacity? 8 A. No. 9 Q. Have you ever been involved in a 10 company's analysis of safety data regarding a 11 cosmetic? 12 A. No. 13 Q. You have never worked for FDA, 14 correct? 15 A. Correct. 16 Q. Have you ever worked for any 17 governmental agency, that is, been employed by a 18 governmental agency? 19 A. Yes. Oh, employed by a government 20 agency. No. 21 Q. Have you ever communicated directly | 1 A. Correct. 2 Q. You have never communicated with 3 Health Canada? 4 A. Correct. 5 Q. Have you ever referenced in any 6 publication of yours a finding by Health Canada? 7 A. No. 8 Q. Have you ever referenced in any 9 publication of yours a Health Canada risk 10 assessment? 11 A. Only the report that I currently 12 wrote. 13 Q. My question was specifically as to a 14 publication. 15 Your report has not been published, 16 correct? 17 A. Correct. 18 Q. So have you ever referenced in any 19 publication of yours a Health Canada risk 20 assessment? 21 A. No. |
| 1 Q. Has any cosmetic pharmaceutical or 2 chemical company ever hired you as a consultant on 3 any matter? 4 A. No. 5 Q. Have you ever been employed by a 6 pharmaceutical medical device consumer product or 7 chemical company in any capacity? 8 A. No. 9 Q. Have you ever been involved in a 10 company's analysis of safety data regarding a 11 cosmetic? 12 A. No. 13 Q. You have never worked for FDA, 14 correct? 15 A. Correct. 16 Q. Have you ever worked for any 17 governmental agency, that is, been employed by a 18 governmental agency? 19 A. Yes. Oh, employed by a government 20 agency. No. 21 Q. Have you ever communicated directly 22 with anyone at FDA regarding a cosmetic including | 1 A. Correct. 2 Q. You have never communicated with 3 Health Canada? 4 A. Correct. 5 Q. Have you ever referenced in any 6 publication of yours a finding by Health Canada? 7 A. No. 8 Q. Have you ever referenced in any 9 publication of yours a Health Canada risk 10 assessment? 11 A. Only the report that I currently 12 wrote. 13 Q. My question was specifically as to a 14 publication. 15 Your report has not been published, 16 correct? 17 A. Correct. 18 Q. So have you ever referenced in any 19 publication of yours a Health Canada risk 20 assessment? 21 A. No. 22 Q. Do you claim to be an expert in |
| 1 Q. Has any cosmetic pharmaceutical or 2 chemical company ever hired you as a consultant on 3 any matter? 4 A. No. 5 Q. Have you ever been employed by a 6 pharmaceutical medical device consumer product or 7 chemical company in any capacity? 8 A. No. 9 Q. Have you ever been involved in a 10 company's analysis of safety data regarding a 11 cosmetic? 12 A. No. 13 Q. You have never worked for FDA, 14 correct? 15 A. Correct. 16 Q. Have you ever worked for any 17 governmental agency, that is, been employed by a 18 governmental agency? 19 A. Yes. Oh, employed by a government 20 agency. No. 21 Q. Have you ever communicated directly | 1 A. Correct. 2 Q. You have never communicated with 3 Health Canada? 4 A. Correct. 5 Q. Have you ever referenced in any 6 publication of yours a finding by Health Canada? 7 A. No. 8 Q. Have you ever referenced in any 9 publication of yours a Health Canada risk 10 assessment? 11 A. Only the report that I currently 12 wrote. 13 Q. My question was specifically as to a 14 publication. 15 Your report has not been published, 16 correct? 17 A. Correct. 18 Q. So have you ever referenced in any 19 publication of yours a Health Canada risk 20 assessment? 21 A. No. |

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|-----|---|----|---|
| 1 | Q. What is the basis of your expertise? | 1 | doing its screening assessment? In other words, |
| 2 | A. I believe I'm an accomplished | | had you heard about it before you were contacted |
| | epidemiologist that's able to evaluate the | | by plaintiffs' counsel for this litigation? |
| | strengths and limitations of the evaluation of | 4 | A. No, I was not. |
| | scientific literature. | 5 | Q. You have reviewed the screening |
| 6 | Q. My question might be a little bit | | assessment, and from your review, did you note |
| | different. | 7 | |
| 8 | My question is: Are you an expert | 8 | |
| | in the process by which Health Canada goes about | 9 | MR. TISI: Objection. |
| | doing its risk assessments? | 10 | Incomplete. |
| 11 | A. No. | 11 | THE WITNESS: In my review, I |
| 12 | MR. TISI: Objection. Vague. | 12 | did not I only looked at the studies |
| 13 | THE WITNESS: Sorry. | 13 | and the evaluation that they did. I did |
| | BY MR. HEGARTY: | | • |
| | | 14 | not consider who did it, who was paid by |
| 15 | ` | 15 | whom to do what, or anything really |
| 1 | screening assessment for talc, correct? | 16 | regarding litigation. BY MR. HEGARTY: |
| 17 | A. Yes. | | |
| 18 | Q. Did you have any dealings with | 18 | Q. Have you ever cited to litigation |
| 1 | Health Canada as it relates to that screening | | reports in any peer-reviewed publication of yours? |
| | assessment? | 20 | A. No, not that I'm aware of. |
| 21 | A. No. | 21 | Q. Have you ever cited to any expert |
| 22 | Q. Did you read Health Canada's | | litigation testimony in any peer-reviewed |
| 1 | screening assessment for talc prior to being | | publication of yours? |
| 24 | contacted by plaintiffs' counsel about testifying | 24 | A. No. |
| | Page 39 | 1 | Page 41 |
| | as an expert for them in this litigation? | 1 | Q. Do you know whether FDA has ever |
| 2 | A. I did not. | | cited to any litigation expert reports or |
| 3 | Q. Do you know who the authors of | | testimony in making any safety findings or |
| | Health Canada's screening assessment are? | | conclusions? |
| 5 | A. I do not. | 5 | MR. TISI: Objection. |
| 6 | Q. Do you know anyone involved in | 6 | Only if you know. |
| 1 | analyzing the data and putting that screening | 7 | THE WITNESS: No. |
| | assessment together? | | BY MR. HEGARTY: |
| 9 | A. No. | 9 | Q. Have you ever cited to exhibits from |
| 10 | Q. Do you know the expertise of anyone | | depositions in any peer-reviewed publication of |
| | involved in putting the screening assessment | | yours? |
| | together for talc? | 12 | |
| 13 | A. In the Health Canada report? | 13 | Q. Do you think it's appropriate for an |
| 14 | Q. Yes, sir. | | entity such as Health Canada to rely on litigation |
| 15 | A. No. | | reports for purposes of putting together that |
| 16 | Q. Did you review any of the materials | | screening assessment? |
| 1 | submitted to Health Canada as part of that | 17 | MR. TISI: Again, let me |
| | process? | 18 | 3 |
| 19 | A. No. | 19 | |
| 20 | Q. You did not submit any material to | 20 | |
| 1 - | Health Canada as part of the screening assessment | 21 | don't I have no opinion on that. |
| | | | |
| 22 | process, correct? | | BY MR. HEGARTY: |
| | | 23 | BY MR. HEGARTY: Q. I asked you earlier about your consulting work. |

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|--|--|
| 1 Are you currently consulting, | 1 first |
| 2 outside of what we're here to talk about today, | 2 MR. HEGARTY: That's what I |
| 3 cases involving talcum powder use and ovarian | 3 was going to say. Let's go off the |
| 4 cancer? | 4 record. |
| 5 A. No. | 5 (Recess: 9:57 a.m |
| 6 MR. HEGARTY: The next exhibit | 6 10:01 a.m.) |
| 7 I'm going to mark, Dr. Harlow, is a copy | 7 BY MR. HEGARTY: |
| 8 of the CV we were provided in advance of | 8 Q. Dr. Harlow, we took a short break |
| 9 your deposition. It's dated at the top | 9 after you and I discussed when you were first |
| 10 March 2024. | 10 being when you were first contacted about |
| 11 THE WITNESS: Uh-huh. | 11 serving as an expert witness in this litigation, |
| 12 MR. HEGARTY: I'm going to | 12 and in doing so, I want to circle back to your |
| mark that document as Exhibit 3. | 13 invoices that we marked as Exhibit Number 2. |
| 14 (Document marked for | Do you have the three invoices that |
| 15 identification as Harlow Exhibit 3.) | 15 we have been provided dated October 2023, January |
| 16 THE WITNESS: Uh-huh. | 16 2024 and February and January/February 2024? |
| 17 BY MR. HEGARTY: | 17 A. Yes. |
| 18 Q. Is Exhibit 3 your March 2024 | 18 Q. Those have all been marked as |
| 19 curriculum vitae? | 19 Exhibit Number 2 |
| 20 A. Yes. | 20 A. Yes. |
| 21 Q. Does it accurately describe your | |
| 22 education, training, and experience? | 21 Q is that correct? 22 A. Yes. |
| 23 A. Yes. | |
| | |
| | 24 the dates shown on it, can you tell when it was |
| Page 43 | Page 45 |
| 1 necessary to make it current for today? | 1 that you were first contacted about serving as an |
| 2 A. I don't believe so. | 2 expert witness in this litigation? |
| 3 Q. Are your publications list up to | 3 A. Well, it looks like I didn't start |
| 4 date? | 4 doing work until toward the latter part of |
| 5 A. I believe so, though things are | 5 September, but I may have been contacted before. |
| 6 fluid with papers that are currently under review, | 6 I was probably contacted before and didn't get |
| 7 but this is largely correct. | 7 started on doing the work until until then. |
| 8 Q. We are here today to take your | 8 Q. Are you able to recall how long it |
| 9 deposition in the case of In re Johnson & Johnson | 9 was? |
| 10 Talc Litigation MDL, et al. | MR. TISI: I'm sorry. I don't |
| Are you aware that you are | 11 think he was finished. |
| 12 designated as a testifying expert in this case? | 12 BY MR. HEGARTY: |
| A. I know that I am a testifying expert | 13 Q. Oh, I'm sorry. |
| 14 in in this litigation. I don't know who the | 14 A. No. Probably perhaps in August. |
| 15 plaintiffs are. | 15 Q. Looking at Exhibit Number 2, the |
| 16 Q. And we'll cover that here in a | 16 first entry for the October 2023 invoice, it says |
| 17 moment, but when were you first contacted about | 17 "Review of documents provided." |
| 18 serving as an expert in this case? | Who provided documents to you? |
| 19 A. In 2023. | 19 A. Mr. Tisi. |
| 20 Q. Do you recall the exact month and | Q. What documents were you provided? |
| 21 date? | 21 MR. TISI: Objection. I |
| 22 A. I would say perhaps August or | 22 instruct you not to answer what you were |
| 23 September or somewhere in that realm. I could | 23 provided. |
| 24 certainly look on my invoices to see when I | 24 BY MR. HEGARTY: |

| | Page 46 | _ | Page 48 |
|----|--|----|--|
| 1 | Q. Did you ask Mr. Tisi for any | 1 | Q. Looking down at the entries for |
| 2 | , | | October 8th and 9th, it says "Review edits by KJR |
| 3 | litigation? | 3 | and modify report." |
| 4 | MR. TISI: You can answer that | 4 | KJR is Ken Rothman? |
| 5 | question, but no further questions on | 5 | A. Correct. |
| 6 | that. | 6 | Q. How were those edits communicated to |
| 7 | THE WITNESS: Only to the | 7 | you? |
| 8 | extent that that it would be more | 8 | A. We we worked together |
| 9 | efficient with my time if they had the | 9 | collaboratively. We were either in person, but |
| 10 | | 10 | most of the time it was on Zoom. |
| 11 | articles so that I wouldn't have to spend | 11 | Q. Were there drafts prepared that you |
| 12 | , , | 12 | still have of your report? |
| 13 | to pull them all out on my own. | 13 | A. No. We we would modify existing |
| 14 | Even though I did a Medline | 14 | drafts and we would not keep the old ones. |
| 15 | search on the literature, I tried to be | 15 | Q. The entry for October 10, 2023 says |
| 16 | 3 | 16 | "Met with KJR and then modified report." |
| 17 | BY MR. HEGARTY: | 17 | Did you meet with him in person? |
| 18 | Q. How many documents were you provided | 18 | A. I don't recall. |
| 19 | by Mr. Tisi's office? | 19 | Q. Looking at the bottom, under Total |
| 20 | A. I don't recall, but certainly no | 20 | it says "Total received: 9,000. Balance due: |
| 21 | not no more than what I've already what I | 21 | |
| 22 | already have here. So. | 22 | Is that 9,000 not a retainer? |
| 23 | Q. You say what you already have here. | 23 | A. No, it is not a retainer. |
| 24 | You're referring to the two | 24 | Q. Where is that where did that |
| | Page 47 | | Page 49 |
| | notebooks we've marked as Exhibit Number 2? | | 9,000 come from? |
| 2 | A. The two notebooks, yes. | 2 | A. It was the first installment. I |
| 3 | Q. If you had the time, could you go | | originally was charging \$400 an hour and after |
| | through the notebooks and identify which documents | | discussion realized that I was underestimating my |
| | that Mr. Tisi provided to you and which you | | expert my expertise, and so I raised my hourly |
| | obtained on your own? | | rate to \$600. |
| 7 | A. I don't believe I'd be able to make | 7 | Q. What does it mean on the first page |
| _ | that separation. | | of Exhibit Number 2 where it says "Total received: |
| 9 | Q. The next two entries well, first | | 9,000. Balance due: 4500"? |
| | of all, before I go there, did you read all the | 10 | A. The 9,000 was equated to these hours |
| | documents that Mr. Tisi's office provided to you? | | at a rate of \$400 per hour, and then when we |
| 12 | | | changed it to 600, that's what was added in. |
| | provided, yes. | 13 | Q. Please turn to your January 2024 |
| 14 | 1 | | invoice, invoice number 2. |
| | "Review of current epi studies." | 15 | A. Yes. |
| 16 | How many epi studies does that refer | 16 | Q. At the top, the entry dated |
| | to? | | October 23, 2023, it says "Discussion of Draft |
| 18 | A. I don't recall. | | Report Submitted." |
| 19 | Q. The next one says "Review of current | 19 | Who was that discussion with? |
| 20 | literature." | 20 | A. With Mr. Tisi and his colleagues. |
| 21 | Is that different than epi studies? | 21 | Q. What other who what colleagues |
| | A. It's a combination of both, of both | 22 | besides Mr. Tisi? |
| 22 | | | |
| 23 | epi studies and other articles in the scientific literature that are relevant. | 23 | A. I believe Michelle. I believe it |

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| 1 | Page 50 | | Page 52 |
|--|---|--|---|
| | just I don't exactly recall. | 1 | the colleagues involved in that deposition |
| 2 | Q. The next several entries say "Report | 2 | preparation meeting? |
| 3 | Modification." | 3 | A. I'm sorry. I'm not that good with |
| 4 | What does "report modification" | 4 | names. (Laugh). |
| 5 | mean? | 5 | Q. Was that deposition preparation |
| 6 | A. We we modified based on other | 6 | meeting in person or by phone? |
| 7 | review of our report by Mr. Tisi and his | 7 | A. By by Zoom. |
| 8 | colleagues. Not to change our opinions about | 8 | Q. Please turn to your invoice |
| 9 | anything but to elaborate in certain areas. | 9 | number 3, January/February 2024. |
| 10 | Q. With regard to the "Discussion of | 10 | A. Uh-huh. |
| 11 | Draft Report Submitted," was Dr. Rothman involved | 11 | Q. At the top, the entry for January 8, |
| 12 | in that discussion, too? | 12 | 2024 says "Meeting to discuss deposition." |
| 13 | A. Yes. | 13 | Was that again with Mr. Tisi and |
| 14 | Q. The next several entries regarding | 14 | colleagues? |
| | revisions and modifications of your report, did | 15 | A. Yes. |
| | you do this, those revisions and modifications, | 16 | • |
| | using the same process you told me a moment ago | 17 | A. On Zoom. All of our meetings have |
| 18 | where you were working with a living document? | | been on Zoom, other than when I came down to DC. |
| 19 | A. Yes. | 19 | Q. With regard to your coming down to |
| 20 | Q. The 11/8/2023 entry says "Meeting | | DC, when did you come down to DC? |
| | with Ken and additional revisions." | 21 | A. Actually, may I correct that |
| 22 | Was that an in-person meeting? | 1 | response? |
| 23 | A. I don't recall. | 23 | Q. Sure. |
| 24 | Q. The November 10, 2023 entry says | 24 | A. I did have an in-person meeting the |
| | Page 51 | | Page 53 |
| 1 | E | | week before I came down in Boston with Mr. Tisi |
| 2 | 2 | 2 | and Michelle, and then and then this week when |
| 3 | A. Mr. Tisi and his colleagues. | 1 | |
| l . | | 3 | I came down. |
| 4 | Q. Do you recall the names of any of | 4 | I came down. Q. How long was that the meeting last |
| 5 | Q. Do you recall the names of any of his colleagues? | 4 5 | I came down. Q. How long was that the meeting last week? |
| 4 5 6 | Q. Do you recall the names of any of his colleagues?A. Again, it would it would I | 4 5 6 | I came down. Q. How long was that the meeting last week? A. About seven hours. |
| 4 5 6 7 | Q. Do you recall the names of any of his colleagues? A. Again, it would it would I don't I mean, it would possibly be Ms | 4 5 6 7 | I came down. Q. How long was that the meeting last week? A. About seven hours. Q. You said you came down from Boston |
| 4 5 6 7 8 | Q. Do you recall the names of any of his colleagues? A. Again, it would it would I don't I mean, it would possibly be Ms Ms. O'Dell and Michelle. There might have bee | 4 5 6 7 n 8 | I came down. Q. How long was that the meeting last week? A. About seven hours. Q. You said you came down from Boston to DC yesterday; is that correct? |
| 4 5 6 7 8 9 | Q. Do you recall the names of any of his colleagues? A. Again, it would it would I don't I mean, it would possibly be Ms Ms. O'Dell and Michelle. There might have bee other people on the call with us. | 4 5 6 7 n 8 9 | I came down. Q. How long was that the meeting last week? A. About seven hours. Q. You said you came down from Boston to DC yesterday; is that correct? A. On Monday. |
| 4 5 6 7 8 9 10 | Q. Do you recall the names of any of his colleagues? A. Again, it would it would I don't I mean, it would possibly be Ms Ms. O'Dell and Michelle. There might have bee other people on the call with us. Q. That was what I was going to ask you | 4 5 6 7 n 8 9 | I came down. Q. How long was that the meeting last week? A. About seven hours. Q. You said you came down from Boston to DC yesterday; is that correct? A. On Monday. Q. On Monday. |
| 4 5 6 7 8 9 10 11 | Q. Do you recall the names of any of his colleagues? A. Again, it would it would I don't I mean, it would possibly be Ms Ms. O'Dell and Michelle. There might have bee other people on the call with us. Q. That was what I was going to ask you next. | 4 5 6 7 n 8 9 10 | I came down. Q. How long was that the meeting last week? A. About seven hours. Q. You said you came down from Boston to DC yesterday; is that correct? A. On Monday. Q. On Monday. Did you meet with Mr. Tisi and |
| 4 5 6 7 8 9 10 11 12 | Q. Do you recall the names of any of his colleagues? A. Again, it would it would I don't I mean, it would possibly be Ms Ms. O'Dell and Michelle. There might have bee other people on the call with us. Q. That was what I was going to ask you next. Was that legal team meeting in | 4 5 6 7 n 8 9 10 11 12 | I came down. Q. How long was that the meeting last week? A. About seven hours. Q. You said you came down from Boston to DC yesterday; is that correct? A. On Monday. Q. On Monday. Did you meet with Mr. Tisi and Ms. Parfitt yesterday? |
| 4 5 6 7 8 9 10 11 12 13 | Q. Do you recall the names of any of his colleagues? A. Again, it would it would I don't I mean, it would possibly be Ms Ms. O'Dell and Michelle. There might have bee other people on the call with us. Q. That was what I was going to ask you next. Was that legal team meeting in person or on the phone? | 4 5 6 7 n 8 9 10 11 12 13 | I came down. Q. How long was that the meeting last week? A. About seven hours. Q. You said you came down from Boston to DC yesterday; is that correct? A. On Monday. Q. On Monday. Did you meet with Mr. Tisi and Ms. Parfitt yesterday? A. Yesterday evening, yes. |
| 4 5 6 7 8 9 10 11 12 13 14 | Q. Do you recall the names of any of his colleagues? A. Again, it would it would I don't I mean, it would possibly be Ms Ms. O'Dell and Michelle. There might have bee other people on the call with us. Q. That was what I was going to ask you next. Was that legal team meeting in person or on the phone? A. Zoom. | 4 5 6 7 n 8 9 10 11 12 13 14 | I came down. Q. How long was that the meeting last week? A. About seven hours. Q. You said you came down from Boston to DC yesterday; is that correct? A. On Monday. Q. On Monday. Did you meet with Mr. Tisi and Ms. Parfitt yesterday? A. Yesterday evening, yes. Q. How long did you meet yesterday |
| 4 5 6 7 8 9 10 11 12 13 14 15 | Q. Do you recall the names of any of his colleagues? A. Again, it would it would I don't I mean, it would possibly be Ms Ms. O'Dell and Michelle. There might have bee other people on the call with us. Q. That was what I was going to ask you next. Was that legal team meeting in person or on the phone? A. Zoom. Q. The final entry on that invoice says | 4 5 6 7 nn 8 9 10 11 12 13 14 15 | I came down. Q. How long was that the meeting last week? A. About seven hours. Q. You said you came down from Boston to DC yesterday; is that correct? A. On Monday. Q. On Monday. Did you meet with Mr. Tisi and Ms. Parfitt yesterday? A. Yesterday evening, yes. Q. How long did you meet yesterday evening? |
| 4 5 6 7 8 9 10 11 12 13 14 15 16 | Q. Do you recall the names of any of his colleagues? A. Again, it would it would I don't I mean, it would possibly be Ms Ms. O'Dell and Michelle. There might have bee other people on the call with us. Q. That was what I was going to ask you next. Was that legal team meeting in person or on the phone? A. Zoom. Q. The final entry on that invoice says "Deposition preparation." | 4 5 6 7 nn 8 9 10 11 12 13 14 15 16 | I came down. Q. How long was that the meeting last week? A. About seven hours. Q. You said you came down from Boston to DC yesterday; is that correct? A. On Monday. Q. On Monday. Did you meet with Mr. Tisi and Ms. Parfitt yesterday? A. Yesterday evening, yes. Q. How long did you meet yesterday evening? A. About one to two hours. |
| 4 5 6 7 8 9 10 11 12 13 14 15 16 17 | Q. Do you recall the names of any of his colleagues? A. Again, it would it would I don't I mean, it would possibly be Ms Ms. O'Dell and Michelle. There might have bee other people on the call with us. Q. That was what I was going to ask you next. Was that legal team meeting in person or on the phone? A. Zoom. Q. The final entry on that invoice says "Deposition preparation." Was that deposition preparation with | 4 5 6 7 n 8 9 10 11 12 13 14 15 16 17 | I came down. Q. How long was that the meeting last week? A. About seven hours. Q. You said you came down from Boston to DC yesterday; is that correct? A. On Monday. Q. On Monday. Did you meet with Mr. Tisi and Ms. Parfitt yesterday? A. Yesterday evening, yes. Q. How long did you meet yesterday evening? A. About one to two hours. Q. The meeting yesterday and the |
| 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 | Q. Do you recall the names of any of his colleagues? A. Again, it would it would I don't I mean, it would possibly be Ms Ms. O'Dell and Michelle. There might have bee other people on the call with us. Q. That was what I was going to ask you next. Was that legal team meeting in person or on the phone? A. Zoom. Q. The final entry on that invoice says "Deposition preparation." Was that deposition preparation with someone else | 4 5 6 7 n 8 9 10 11 12 13 14 15 16 17 18 | I came down. Q. How long was that the meeting last week? A. About seven hours. Q. You said you came down from Boston to DC yesterday; is that correct? A. On Monday. Q. On Monday. Did you meet with Mr. Tisi and Ms. Parfitt yesterday? A. Yesterday evening, yes. Q. How long did you meet yesterday evening? A. About one to two hours. Q. The meeting yesterday and the meeting last week were the only in-person meetings |
| 44 55 66 77 88 9 10 11 12 13 14 15 16 17 18 19 | Q. Do you recall the names of any of his colleagues? A. Again, it would it would I don't I mean, it would possibly be Ms Ms. O'Dell and Michelle. There might have bee other people on the call with us. Q. That was what I was going to ask you next. Was that legal team meeting in person or on the phone? A. Zoom. Q. The final entry on that invoice says "Deposition preparation." Was that deposition preparation with someone else A. Yes. | 14 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 | I came down. Q. How long was that the meeting last week? A. About seven hours. Q. You said you came down from Boston to DC yesterday; is that correct? A. On Monday. Q. On Monday. Did you meet with Mr. Tisi and Ms. Parfitt yesterday? A. Yesterday evening, yes. Q. How long did you meet yesterday evening? A. About one to two hours. Q. The meeting yesterday and the meeting last week were the only in-person meetings you had with Mr. Tisi and Ms. Parfitt? |
| 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 | Q. Do you recall the names of any of his colleagues? A. Again, it would it would I don't I mean, it would possibly be Ms Ms. O'Dell and Michelle. There might have bee other people on the call with us. Q. That was what I was going to ask you next. Was that legal team meeting in person or on the phone? A. Zoom. Q. The final entry on that invoice says "Deposition preparation." Was that deposition preparation with someone else A. Yes. Q or was that on your own? | 4 5 6 7 n 8 9 10 11 12 13 14 15 16 17 18 19 20 | I came down. Q. How long was that the meeting last week? A. About seven hours. Q. You said you came down from Boston to DC yesterday; is that correct? A. On Monday. Q. On Monday. Did you meet with Mr. Tisi and Ms. Parfitt yesterday? A. Yesterday evening, yes. Q. How long did you meet yesterday evening? A. About one to two hours. Q. The meeting yesterday and the meeting last week were the only in-person meetings you had with Mr. Tisi and Ms. Parfitt? A. That's correct. |
| 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 | Q. Do you recall the names of any of his colleagues? A. Again, it would it would I don't I mean, it would possibly be Ms Ms. O'Dell and Michelle. There might have bee other people on the call with us. Q. That was what I was going to ask you next. Was that legal team meeting in person or on the phone? A. Zoom. Q. The final entry on that invoice says "Deposition preparation." Was that deposition preparation with someone else A. Yes. Q or was that on your own? A. No, no. Yes. That would I'm | 4 5 6 7 n 8 9 10 11 12 13 14 15 16 17 18 19 20 21 | I came down. Q. How long was that the meeting last week? A. About seven hours. Q. You said you came down from Boston to DC yesterday; is that correct? A. On Monday. Q. On Monday. Did you meet with Mr. Tisi and Ms. Parfitt yesterday? A. Yesterday evening, yes. Q. How long did you meet yesterday evening? A. About one to two hours. Q. The meeting yesterday and the meeting last week were the only in-person meetings you had with Mr. Tisi and Ms. Parfitt? A. That's correct. Q. The other entries here with regard |
| 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 | Q. Do you recall the names of any of his colleagues? A. Again, it would it would I don't I mean, it would possibly be Ms Ms. O'Dell and Michelle. There might have bee other people on the call with us. Q. That was what I was going to ask you next. Was that legal team meeting in person or on the phone? A. Zoom. Q. The final entry on that invoice says "Deposition preparation." Was that deposition preparation with someone else A. Yes. Q or was that on your own? A. No, no. Yes. That would I'm sorry. That was not on my own. It was with | 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 | I came down. Q. How long was that the meeting last week? A. About seven hours. Q. You said you came down from Boston to DC yesterday; is that correct? A. On Monday. Q. On Monday. Did you meet with Mr. Tisi and Ms. Parfitt yesterday? A. Yesterday evening, yes. Q. How long did you meet yesterday evening? A. About one to two hours. Q. The meeting yesterday and the meeting last week were the only in-person meetings you had with Mr. Tisi and Ms. Parfitt? A. That's correct. Q. The other entries here with regard to deposition preparation with lawyers, for |
| 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 | Q. Do you recall the names of any of his colleagues? A. Again, it would it would I don't I mean, it would possibly be Ms Ms. O'Dell and Michelle. There might have bee other people on the call with us. Q. That was what I was going to ask you next. Was that legal team meeting in person or on the phone? A. Zoom. Q. The final entry on that invoice says "Deposition preparation." Was that deposition preparation with someone else A. Yes. Q or was that on your own? A. No, no. Yes. That would I'm sorry. That was not on my own. It was with Mr. Tisi and colleagues. | 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 | I came down. Q. How long was that the meeting last week? A. About seven hours. Q. You said you came down from Boston to DC yesterday; is that correct? A. On Monday. Q. On Monday. Did you meet with Mr. Tisi and Ms. Parfitt yesterday? A. Yesterday evening, yes. Q. How long did you meet yesterday evening? A. About one to two hours. Q. The meeting yesterday and the meeting last week were the only in-person meetings you had with Mr. Tisi and Ms. Parfitt? A. That's correct. Q. The other entries here with regard to deposition preparation with lawyers, for example, that was again by Zoom? |

| | Page 54 | | Page 56 |
|----|--|----|--|
| 1 | Q. The depo prep meeting with lawyers, | 1 | since February 29, 2024? |
| 2 | that was by Zoom? | 2 | A. Maybe 20. It might be more because |
| 3 | A. That's correct. | 3 | of the long session that we had last week and, |
| 4 | Oh, there's the name of the other | 4 | obviously, what is occurring today. So, but other |
| 5 | deposition that I had reviewed. | 5 | than that, I would say it is less than 20 hours. |
| 6 | Q. Who is that? | 6 | Q. Going back to when you were first |
| 7 | A. Dr. Osan. | 7 | contacted about serving as an expert witness in |
| 8 | Q. This invoice also refers to you | 8 | this case, who contacted you? |
| 9 | reviewing Dr. Osan's report, correct? | 9 | A. Dr. Rothman. |
| 10 | A. That's correct. | 10 | Q. Did he tell you who had contacted |
| 11 | Q. Did you review her expert report for | 11 | him about serving as an expert witness in this |
| 12 | this litigation? | 12 | litigation? |
| 13 | A. I believe I reviewed the deposition. | 13 | A. I believe he must have mentioned |
| 14 | Q. So where it says "report," it should | 14 | he mentioned the name of the people he was working |
| 15 | be deposition? | 15 | with. |
| 16 | A. I think it should be, actually. | 16 | Q. Do you recall whose name he |
| 17 | Q. The entry of February 28, 2024 | 17 | mentioned, or names? |
| 18 | refers to your review of Dr. Moorman's deposition, | 18 | A. I really I really don't recall |
| 19 | which you talked about earlier, right? | 19 | that, until we had our first meeting, and then I |
| 20 | A. Yes. | 20 | was introduced to Mr. Tisi. |
| 21 | Q. There's also the last entry or | 21 | Q. Was your first meeting prior to this |
| 22 | let me start over. | 22 | November this September 26, 2023 date on your |
| 23 | The last entry refers to "Deposition | 23 | first invoice? |
| 24 | preparation with lawyers." | 24 | A. No, it would not have been because I |
| | Page 55 | | Page 57 |
| 1 | Was that again Mr. Tisi and | 1 | would have invoiced for it. |
| 2 | colleagues? | 2 | Q. What did Dr. Rothman initially tell |
| 3 | A. Yes. | | you about potentially serving as an expert witness |
| 4 | Q. Again by Zoom? | 4 | in this litigation? |
| 5 | A. Yes. | 5 | A. He didn't specifically ask me to be |
| 6 | Q. With regard to Dr. Osan, was she the | 6 | an expert witness. He asked me to work with him |
| 7 | only defense expert's testimony that you have | 7 | on preparing a report on the current scientific |
| 8 | reviewed for your work on this case? | 8 | evidence. |
| 9 | A. Yes. | 9 | Q. When did you become aware that that |
| 10 | Q. With regard to the invoices that | 10 | report would be an expert report for litigation |
| 1 | we've been looking at, have you been paid for the | 11 | purposes? |
| 12 | amounts shown in the invoices? | 12 | A. After discussion with Mr. Tisi and |
| 13 | A. Yes. | 13 | others. |
| 14 | Q. Have you prepared any additional | 14 | Q. What did you understand prior to the |
| 1 | invoices for further work you have done since the | 15 | discussion with Mr. Tisi and others about why you |
| 16 | date of this last invoice? | 16 | and Dr. Rothman were writing a report about talcum |
| 17 | A. I have not submitted any invoices. | 17 | powder and ovarian cancer? |
| 18 | Q. Have you recorded the number of | 18 | A. Oh, I knew it was with respect to |
| 19 | hours you have spent working on this litigation | 19 | litigation. |
| 20 | since September I'm sorry since February 29, | 20 | Q. There was never an understanding |
| | 2024? | 21 | that this would be for publication in a |
| 22 | A. Yes. | | peer-reviewed journal, correct? |
| 23 | Q. Do you know approximately how many | 23 | A. That is correct. |
| 24 | hours you have spent working on this litigation | 24 | Q. Prior to Dr. Rothman contacting you |

| 1 | Page 58 | 1 | Page 60 |
|--|---|--|---|
| 1 | about potentially serving as an expert witness in this litigation, or what ultimately became serving | | And then I had not done any work as after, I believe, 2017. |
| 1 | as an expert witness in this litigation, had you | $\frac{2}{3}$ | Q. Do you recall how much you invoiced |
| 1 | ever been contacted by any plaintiff's lawyer | 4 | • |
| 1 | about serving as an expert witness in a case | 5 | A. I would say it was less than |
| 1 | involving talcum powder use? | 6 | \$20,000. |
| 7 | A. Not as an expert witness. | 7 | Q. How much were you charging an hour |
| 8 | Q. Had you ever been contacted by any | 8 | |
| 1 | lawyer about cases involving talcum powder use to | 9 | A. I would have to go back and look, |
| 1 | serve in any capacity? | 1 | but it was less than 400. It might have been 200 |
| 11 | A. Yes. | 1 | I don't recall. It was probably in that range of |
| 12 | Q. Who contacted you about serving in | 1 | 2 to 400. |
| 13 | any capacity in cases involving talcum powder use? | 13 | Q. To your knowledge, were you ever |
| 14 | A. I | | disclosed as a testifying expert by these lawyers |
| 15 | MR. TISI: I'm sorry. What | 1 | or other lawyers prior to your disclosure in this |
| 16 | was the question? I'm sorry. The phone | | case? |
| 17 | went off so I missed it. | 17 | A. Not that I'm aware of. |
| 18 | MR. HEGARTY: Sure. | 18 | MR. HEGARTY: I'm going to |
| | BY MR. HEGARTY: | 19 | |
| 20 | Q. Who contacted you initially or | 20 | • |
| 21 | strike that. | 21 | (Document marked for |
| 22 | Who contacted you about serving in | 22 | identification as Harlow Exhibit 4.) |
| 23 | the capacity as a consultant in cases involving | 23 | BY MR. HEGARTY: |
| 24 | talcum powder use? | 24 | Q. This is a designation of well, |
| | Page 59 | | D (1 |
| | | 1 | Page 61 |
| 1 | | 1 | Page 61 this is called this is a document titled |
| 1 2 | MR. TISI: You may answer that question. | | _ |
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| 3 | MR. TISI: You may answer that question. THE WITNESS: Members of | 2 3 | this is called this is a document titled "Plaintiff's Designation of Affirmative Experts" in the case of Chakalos versus Johnson & Johnson. |
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| 1 | De (2) | | Prov. CA |
|--|---|---|--|
| | Q. Yes, Doctor. | 1 | Page 64 THE WITNESS: Yes. |
| 2 | A. Oh, I'm sorry. | $\frac{1}{2}$ | BY MR. HEGARTY: |
| 3 | I believe the only two that I recall | 3 | Q. What was that opinion? |
| | are Meghan Carter and Carmen Scott. | 4 | A. I don't |
| 5 | Q. Do you have any recollection of a | 5 | MR. TISI: Objection. |
| | case called Chakalos versus Johnson & Johnson | | Whatever yeah. |
| 7 | A. I do. | 7 | THE WITNESS: I don't recall. |
| 8 | Q. Did you review Ms. Chakalos's | 8 | MR. TISI: You may answer. |
| | medical records? | 9 | THE WITNESS: I don't recall. |
| 10 | A. I did. | 10 | MR. TISI: Then that's fine. |
| 11 | Q. To your knowledge, though, you were | 11 | Let me just object because I |
| | unaware that you had been designated as a | 12 | don't know that he knows he was |
| | testifying expert in that case; is that correct? | 13 | designated as an expert. You asked him |
| 14 | A. That's correct. | 14 | that question, but he I would object, |
| 15 | Q. Did you prepare an expert report on | 15 | obviously, to any communications that he |
| | the Chakalos case? | 16 | had with the lawyer on the basis of |
| 17 | MR. TISI: Let me just go | 17 | whatever Rule 26 privilege is. |
| 18 | though this. You can go off the record. | 18 | Because I don't want to put |
| 19 | MR. HEGARTY: Sure. Go off | 19 | words in his mouth, but I believe he |
| 20 | the record. | 20 | thought he was a consultant, but go |
| 21 | (Recess: 10:19 a.m | 21 | ahead. |
| 22 | 10:28 a.m.) | 22 | BY MR. HEGARTY: |
| 23 | MR. HEGARTY: We are back on | 23 | Q. This can be a yes or no answer. |
| 24 | the record. | 24 | Do you recall if you reviewed any |
| | Page 63 | | Page 65 |
| 1 | I think there was a discussion | 1 | other patient's medical records when you served in |
| 2 | prior to us starting about making a | 2 | this consulting capacity besides Ms. Chakalos's |
| 3 | statement as it relates to the New Jersey | 3 | medical records? |
| 4 | litigation? | 4 | A. I believe I did. |
| 5 | MR. TISI: Yes. First of all, | 5 | Q. Do you recall the number of other |
| 6 | we have agreed that an objection by one | 6 | |
| | is an objection by all. So that Tracy's | | women's records you reviewed? |
| 7 | is an objection by an. So that Tracy's | 7 | women's records you reviewed? A. I would say it's no more than two or |
| 7 8 | objections would be preserved. | 7 8 | • |
| | • | 7 8 9 | A. I would say it's no more than two or |
| 8 | objections would be preserved. | 9 | A. I would say it's no more than two or three. |
| 8 9 10 11 | objections would be preserved. And I don't know if there was a question pending at the time that we took a break. | 9 10 | A. I would say it's no more than two or three. Q. Was it your understanding when you |
| 8 9 10 11 12 | objections would be preserved. And I don't know if there was a question pending at the time that we took a break. MR. HEGARTY: Was there a | 9 10 | A. I would say it's no more than two or three. Q. Was it your understanding when you reviewed their records that you had the totality |
| 8 9 10 11 12 13 | objections would be preserved. And I don't know if there was a question pending at the time that we took a break. MR. HEGARTY: Was there a question pending? | 9 10 11 12 13 | A. I would say it's no more than two or three. Q. Was it your understanding when you reviewed their records that you had the totality of their medical records? A. Yes. Q. With regard to those review of those |
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| 8 9 10 11 12 13 14 15 16 17 18 19 20 21 | objections would be preserved. And I don't know if there was a question pending at the time that we took a break. MR. HEGARTY: Was there a question pending? (The reporter read the record on page 62 lines 15-16.) MR. HEGARTY: Okay. Okay. BY MR. HEGARTY: Q. You can answer that question. A. Yeah. I don't believe I prepared an expert report on that case. Q. Did you form an opinion as to the | 9 10 11 12 13 14 15 16 17 18 19 20 21 | A. I would say it's no more than two or three. Q. Was it your understanding when you reviewed their records that you had the totality of their medical records? A. Yes. Q. With regard to those review of those two or three other women's records, was that also back in 2015 and 2016? A. It was during that time period, yes. Q. Since your consultation back in that time period of 2015-2016, have you reviewed the medical records of any other woman who you understood is claiming ovarian cancer from talcum powder use? |
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| 8 9 10 11 12 13 14 15 16 17 18 19 20 21 | objections would be preserved. And I don't know if there was a question pending at the time that we took a break. MR. HEGARTY: Was there a question pending? (The reporter read the record on page 62 lines 15-16.) MR. HEGARTY: Okay. Okay. BY MR. HEGARTY: Q. You can answer that question. A. Yeah. I don't believe I prepared an expert report on that case. Q. Did you form an opinion as to the | 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 | A. I would say it's no more than two or three. Q. Was it your understanding when you reviewed their records that you had the totality of their medical records? A. Yes. Q. With regard to those review of those two or three other women's records, was that also back in 2015 and 2016? A. It was during that time period, yes. Q. Since your consultation back in that time period of 2015-2016, have you reviewed the medical records of any other woman who you understood is claiming ovarian cancer from talcum powder use? |

| Page 66 | | Page 68 |
|---|--|--|
| 1 that are shown in the document I've marked as | 1 | this case besides in your capacity as a consultant |
| 2 Exhibit Number 4? | | and expert witness? |
| 3 A. Not that I'm aware of. | 3 | A. No. |
| 4 Q. When did you understand that | 4 | Q. You know Dr. Daniel Cramer, correct |
| 5 consulting relationship ended? | 5 | A. Yes. |
| 6 A. At the time of my last submission of | 6 | Q. Do you know him socially as well as |
| 7 information. I just never received any further | 7 | professionally? |
| 8 communication from them. | 8 | A. Not recently. |
| 9 Q. Was the last submission you made | 9 | Q. Not recently socially? |
| 10 before the COVID shutdown in 2020? | 10 | A. Correct. When we worked together, |
| 11 A. Oh, well before that. Well before | 1 | we ran an office together, and there were times |
| 12 that. | | when we would have social events with our staff |
| 13 Q. Do you recall how long, how much | | and colleagues. |
| 14 before? | 14 | Q. Are you aware that he has served as |
| 15 A. Again, it was all during this period | 1 | an expert witness for plaintiffs' lawyers in cases |
| 16 of time, 2015 to 2017, something like that. I | | involving talcum powder use? |
| 17 don't believe we shut down on COVID until 2019 was | | A. Yes. |
| 18 it? | 18 | Q. Did you know that because of what he |
| | 1 | told you? |
| 19 Q. 2020. 20 A. 2020, yeah. | $\begin{vmatrix} 19\\20 \end{vmatrix}$ | A. Yes. |
| 21 Q. Going back to your initial contact | 21 | Q. You also know Dr. John Godleski, |
| | $\begin{vmatrix} 21\\22\end{vmatrix}$ | - |
| 22 with Dr. Rothman about serving as an expert 23 witness in this case | 23 | A. The name doesn't ring a bell. |
| | 23 | Q. I'm going to read you a list of |
| · · · · · · · · · · · · · · · · · · · | 24 | Q. I'm going to read you a fist of |
| Page 67 | | Page 69 |
| 1 this? | | other plaintiffs' experts that have been |
| 2 MR. HEGARTY: I'm done with | 1 | designated in this case. Tell me if you know them |
| 3 that. | | |
| 4 THE WITNESS: Should I give | 4 | Dr. McTiernan? |
| 5 this back to you? | 5 | A. I know of her, and she and I trained |
| 6 BY MR. HEGARTY: | _ | at the same time as the University of Washington. |
| 7 Q. You can keep those over on that | 7 | Q. Do you know Dr. Siemiatycki? |
| 8 side. | 8 | A. I do not know him. I know of him. |
| 9 MR. TISI: Let me kind of keep | 9 | Q. Do you know Dr. Moorman? |
| track of your exhibits. | 10 | A. I do not know her. |
| 11 THE WITNESS: Okay. | 11 | Q. Do you know Dr. Clarke-Pearson? |
| 12 BY MR. HEGARTY: | 12 | A. No. |
| 13 Q. Going back to your initial contact | 13 | Q. He's a gynecologic oncologist. |
| 14 with Dr. Rothman about serving as an expert | 14 | A. No. |
| 15 witness in this litigation, did he encourage you | 15 | Q. Do you know Dr. Cote? |
| 16 to serve as an expert witness? | 16 | A. No. |
| 17 A. No. | 17 | Q. Do you know Dr. Sonal Singh? |
| | 18 | A. No. |
| 18 Q. How did let me strike that. | | Q. Do you know Dr. Smith-Bindman? |
| Apart from anything that you were | 19 | • |
| Apart from anything that you were 20 told by attorneys, do you know how Dr. Rothma | n20 | A. No. |
| Apart from anything that you were 20 told by attorneys, do you know how Dr. Rothma 21 came to be contacted in the first place? | n20 21 | - |
| Apart from anything that you were 20 told by attorneys, do you know how Dr. Rothma 21 came to be contacted in the first place? 22 A. No. | n20 | A. No. |
| Apart from anything that you were 20 told by attorneys, do you know how Dr. Rothma 21 came to be contacted in the first place? | n20 21 | A. No.Q. Do you Dr. Roberta Ness? |

| | Page 70 | | Page 72 |
|-----|--|----------------|---|
| 1 | 1 | | have been involved, and my main contact is with |
| | on committees. We have attended the same meetings | | Mr. Tisi and Ms. Parfitt. |
| | often. And so when I see her in those capacity, | 3 | Q. During that initial discussion you |
| | we're very cordial professionally, but never had | 4 | , , |
| 5 | any kind of social event with her. | 5 | 1 1 |
| 6 | | 6 | |
| | an expert witness for plaintiffs in talcum powder | 7 | MR. TISI: Objection. |
| 8 | cases? | 8 | Mischaracterizes his prior testimony. He |
| 9 | A. Yes. | 9 | said he was requested to write a report. |
| 10 | Q. How do you know that? | 10 | BY MR. HEGARTY: |
| 11 | A. I was told. | 11 | Q. You can answer. |
| 12 | Q. Were you told that by Dr. Ness? | 12 | A. No, I was not asked by Dr. Rothman |
| 13 | A. No. | 13 | to serve as an expert witness. |
| 14 | Q. Were you told that by attorneys in | 14 | Q. At what point in time did you agree |
| 15 | this case? | 15 | relative to your invoice dates to serve as an |
| 16 | A. Yes. | 16 | expert witness for plaintiffs in this litigation? |
| 17 | Q. Have you ever talked to | 17 | A. After Dr. Rothman and I had |
| 18 | - | 18 | completed our report. |
| 19 | by the way. Go ahead. | 19 | Q. What when from the invoices we |
| 20 | BY MR. HEGARTY: | 20 | looked at did you complete your report? |
| 21 | Q. Have you ever talked to Dr. Ness | 21 | A. Can I refer back to the invoices? |
| 22 | about her or you serving as an expert witness in | 22 | Q. Sure. |
| | cases involving talcum powder use? | 23 | MR. TISI: I got them right |
| 24 | | 24 | here. I've given you my copy but |
| | Page 71 | | Page 73 |
| 1 | | 1 | THE WITNESS: No, no. That's |
| 2 | about his experiences in serving as an expert | 2 | okay. |
| | witness in talcum powder cases? | 3 | (Reviews document.) |
| 4 | • | 4 | |
| 5 | | 5 | by the end of November 2023. |
| _ | other colleague of yours, or someone who's in the | | BY MR. HEGARTY: |
| | same profession, ever encouraged you to | 7 | |
| | participate in this litigation as an expert | 1 . | of November 2023 that you agreed to serve as ar |
| | witness? | | expert witness for plaintiffs in this litigation? |
| 10 | | 10 | |
| 11 | Q. Did you consult with anyone outside | | report and it was I was asked to be in that |
| | of attorneys prior to agreeing to serve as an | 1 | capacity. |
| | expert witness in this litigation? | 13 | Q. What did you understand your work to |
| | | | be prior to being asked to serve as an expert |
| 14 | should charge, as I indicated before. | 1 | witness in this litigation? |
| | _ | 16 | _ |
| 16 | · | | |
| | mentioned Ms. Parfitt. You mentioned perhaps | | report on the state of the evidence. |
| | Ms. O'Dell. | 18 | , , |
| 19 | , and the second | 1 | capacity to be in preserving in preparing that |
| | lawyers that you have worked with as part of your | 1 | report? As a consultant, as an expert, retained |
| | involvement in the talcum powder litigation that | | expert witness, or something else? |
| | we're here to talk about today? | 22 | • |
| 23 | A. Only those that are aligned with | $\frac{23}{2}$ | way. I was asked to prepare the report. I was |
| ~ . | 1 501 | | |

24 interested in doing it and -- but I didn't think

24 this group of attorneys here. There are more that

| D 74 | D 76 |
|---|--|
| Page 74 1 about how I would be classified one way or | Page 76 1 asked first by Mr. Tisi and others to be involved |
| 2 another. | 2 MR. HEGARTY: We'll go ahead |
| 3 Q. Now, with regard to what we've been | 3 for purposes of the record to mark your |
| 4 talking about here today and recently in just the | 4 report. We are on Exhibit Number 6. So |
| 5 last few moments, you did review materials that | 1 |
| 6 plaintiffs' counsel provided and that you obtained | |
| 7 yourself and prepared an expert report, correct? | 7 report I want to make clear. |
| 8 A. That's correct. | 8 I'm on Exhibit Number 5? |
| | 9 MS. PARFITT: I have 5. 4 was |
| 9 Q. That expert report is dated 10 November 15, 2023? | |
| · · | |
| J 13 | |
| | |
| Your expert report is dated | expert report we've been provided for you |
| 14 November 15, 2023? | 14 for this case. |
| 15 A. Again, on my copy it just says | 15 (Document marked for |
| 16 November 2023. | 16 identification as Harlow Exhibit 5.) |
| 17 Q. Is there a date at the end with your | 17 BY MR. HEGARTY: |
| 18 signature? | 18 Q. It does have a cover page which you |
| 19 A. Ah. Quite likely. Let me see. | 19 might not have seen before. |
| MR. TISI: I think that was | A. It also looks a lot thicker. |
| 21 the date it was submitted. | MR. TISI: Was Number 3 his |
| THE WITNESS: No, there isn't | 22 CV? |
| 23 a date. | 23 THE WITNESS: Oh, this is |
| 24 BY MR. HEGARTY: | it has my CV in here as well. |
| | |
| Page 75 | |
| 1 Q. You were compensated for the work | 1 MS. PARFITT: Number 3 is his |
| 1 Q. You were compensated for the work 2 you did on your expert report; is that correct? | 1 MS. PARFITT: Number 3 is his 2 CV. CV is separate. |
| Q. You were compensated for the work you did on your expert report; is that correct? A. That's correct. | 1 MS. PARFITT: Number 3 is his 2 CV. CV is separate. 3 BY MR. HEGARTY: |
| Q. You were compensated for the work you did on your expert report; is that correct? A. That's correct. Q. You wrote your expert report with | MS. PARFITT: Number 3 is his CV. CV is separate. BY MR. HEGARTY: Q. So Dr. Harlow I'm sorry, |
| Q. You were compensated for the work you did on your expert report; is that correct? A. That's correct. Q. You wrote your expert report with Dr. Rothman, correct? | MS. PARFITT: Number 3 is his CV. CV is separate. BY MR. HEGARTY: Q. So Dr. Harlow I'm sorry, Dr. Rothman Harlow, with regard to your expert |
| Q. You were compensated for the work you did on your expert report; is that correct? A. That's correct. Q. You wrote your expert report with Dr. Rothman, correct? A. Yes. | 1 MS. PARFITT: Number 3 is his 2 CV. CV is separate. 3 BY MR. HEGARTY: 4 Q. So Dr. Harlow I'm sorry, 5 Dr. Rothman Harlow, with regard to your expert 6 report that we're looking at, Exhibit Number 5 |
| Q. You were compensated for the work you did on your expert report; is that correct? A. That's correct. Q. You wrote your expert report with Dr. Rothman, correct? A. Yes. Q. Are you aware that plaintiffs' | 1 MS. PARFITT: Number 3 is his 2 CV. CV is separate. 3 BY MR. HEGARTY: 4 Q. So Dr. Harlow I'm sorry, 5 Dr. Rothman Harlow, with regard to your expert 6 report that we're looking at, Exhibit Number 5 7 A. Oh, right. Yeah. |
| Q. You were compensated for the work you did on your expert report; is that correct? A. That's correct. Q. You wrote your expert report with Dr. Rothman, correct? A. Yes. Q. Are you aware that plaintiffs' counsel in this case has withdrawn Dr. Rothman as | 1 MS. PARFITT: Number 3 is his 2 CV. CV is separate. 3 BY MR. HEGARTY: 4 Q. So Dr. Harlow I'm sorry, 5 Dr. Rothman Harlow, with regard to your expert 6 report that we're looking at, Exhibit Number 5 7 A. Oh, right. Yeah. 8 Q is the first part of these pages |
| Q. You were compensated for the work you did on your expert report; is that correct? A. That's correct. Q. You wrote your expert report with Dr. Rothman, correct? A. Yes. Q. Are you aware that plaintiffs' counsel in this case has withdrawn Dr. Rothman as an expert? | 1 MS. PARFITT: Number 3 is his 2 CV. CV is separate. 3 BY MR. HEGARTY: 4 Q. So Dr. Harlow I'm sorry, 5 Dr. Rothman Harlow, with regard to your expert 6 report that we're looking at, Exhibit Number 5 7 A. Oh, right. Yeah. 8 Q is the first part of these pages 9 specifically 1 through 24 your expert report? |
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| Q. You were compensated for the work you did on your expert report; is that correct? A. That's correct. Q. You wrote your expert report with Dr. Rothman, correct? A. Yes. Q. Are you aware that plaintiffs' counsel in this case has withdrawn Dr. Rothman as an expert? A. Yes. Q. Did you discuss Dr. Rothman's | 1 MS. PARFITT: Number 3 is his 2 CV. CV is separate. 3 BY MR. HEGARTY: 4 Q. So Dr. Harlow I'm sorry, 5 Dr. Rothman Harlow, with regard to your expert 6 report that we're looking at, Exhibit Number 5 7 A. Oh, right. Yeah. 8 Q is the first part of these pages 9 specifically 1 through 24 your expert report? 10 A. Yes, it is. 11 Q. It also includes as exhibits your |
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| 1 Q. You were compensated for the work 2 you did on your expert report; is that correct? 3 A. That's correct. 4 Q. You wrote your expert report with 5 Dr. Rothman, correct? 6 A. Yes. 7 Q. Are you aware that plaintiffs' 8 counsel in this case has withdrawn Dr. Rothman as 9 an expert? 10 A. Yes. 11 Q. Did you discuss Dr. Rothman's 12 withdrawal with Dr. Rothman? 13 A. No. | 1 MS. PARFITT: Number 3 is his 2 CV. CV is separate. 3 BY MR. HEGARTY: 4 Q. So Dr. Harlow I'm sorry, 5 Dr. Rothman Harlow, with regard to your expert 6 report that we're looking at, Exhibit Number 5 7 A. Oh, right. Yeah. 8 Q is the first part of these pages 9 specifically 1 through 24 your expert report? 10 A. Yes, it is. 11 Q. It also includes as exhibits your 12 curriculum vitae, the curriculum vitae of and 13 the curriculum vitae of Dr. Harlow, as well as a |
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| 1 Q. You were compensated for the work 2 you did on your expert report; is that correct? 3 A. That's correct. 4 Q. You wrote your expert report with 5 Dr. Rothman, correct? 6 A. Yes. 7 Q. Are you aware that plaintiffs' 8 counsel in this case has withdrawn Dr. Rothman as 9 an expert? 10 A. Yes. 11 Q. Did you discuss Dr. Rothman's 12 withdrawal with Dr. Rothman? 13 A. No. 14 Q. Apart from any discussions you had 15 with counsel for plaintiffs, do you know why he 16 has been withdrawn as an expert witness? 17 A. I do not. 18 Q. Do you know that your report is the 19 only coauthored report in this litigation? | MS. PARFITT: Number 3 is his CV. CV is separate. BY MR. HEGARTY: Q. So Dr. Harlow I'm sorry, Dr. Rothman Harlow, with regard to your expert report that we're looking at, Exhibit Number 5 A. Oh, right. Yeah. Q is the first part of these pages specifically 1 through 24 your expert report? A. Yes, it is. Q. It also includes as exhibits your curriculum vitae, the curriculum vitae of and the curriculum vitae of Dr. Harlow, as well as a list at the end which is a Materials Considered list, Exhibit C. Do you see that? A. I I believe I do. Oh, actually oh, yeah, Exhibit C, Materials Considered. |
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| 1 Q. You were compensated for the work 2 you did on your expert report; is that correct? 3 A. That's correct. 4 Q. You wrote your expert report with 5 Dr. Rothman, correct? 6 A. Yes. 7 Q. Are you aware that plaintiffs' 8 counsel in this case has withdrawn Dr. Rothman as 9 an expert? 10 A. Yes. 11 Q. Did you discuss Dr. Rothman's 12 withdrawal with Dr. Rothman? 13 A. No. 14 Q. Apart from any discussions you had 15 with counsel for plaintiffs, do you know why he 16 has been withdrawn as an expert witness? 17 A. I do not. 18 Q. Do you know that your report is the 19 only coauthored report in this litigation? 20 A. I believe I was told that. 21 Q. Why did you prepare a coauthored | MS. PARFITT: Number 3 is his CV. CV is separate. BY MR. HEGARTY: Q. So Dr. Harlow I'm sorry, Dr. Rothman Harlow, with regard to your expert report that we're looking at, Exhibit Number 5 A. Oh, right. Yeah. Q is the first part of these pages specifically 1 through 24 your expert report? A. Yes, it is. Q. It also includes as exhibits your curriculum vitae, the curriculum vitae of and the curriculum vitae of Dr. Harlow, as well as a list at the end which is a Materials Considered list, Exhibit C. Do you see that? A. I I believe I do. Oh, actually oh, yeah, Exhibit C, Materials Considered. Yes. Uh-huh. Q. How was the work on your report divided between you and Dr. Rothman? |
| 1 Q. You were compensated for the work 2 you did on your expert report; is that correct? 3 A. That's correct. 4 Q. You wrote your expert report with 5 Dr. Rothman, correct? 6 A. Yes. 7 Q. Are you aware that plaintiffs' 8 counsel in this case has withdrawn Dr. Rothman as 9 an expert? 10 A. Yes. 11 Q. Did you discuss Dr. Rothman's 12 withdrawal with Dr. Rothman? 13 A. No. 14 Q. Apart from any discussions you had 15 with counsel for plaintiffs, do you know why he 16 has been withdrawn as an expert witness? 17 A. I do not. 18 Q. Do you know that your report is the 19 only coauthored report in this litigation? 20 A. I believe I was told that. 21 Q. Why did you prepare a coauthored 22 report? | MS. PARFITT: Number 3 is his CV. CV is separate. BY MR. HEGARTY: Q. So Dr. Harlow I'm sorry, Dr. Rothman Harlow, with regard to your expert report that we're looking at, Exhibit Number 5 A. Oh, right. Yeah. Q is the first part of these pages specifically 1 through 24 your expert report? A. Yes, it is. Q. It also includes as exhibits your curriculum vitae, the curriculum vitae of and the curriculum vitae of Dr. Harlow, as well as a list at the end which is a Materials Considered list, Exhibit C. Do you see that? A. I I believe I do. Oh, actually oh, yeah, Exhibit C, Materials Considered. Yes. Uh-huh. Q. How was the work on your report divided between you and Dr. Rothman? A. It was collaborative. |

| | Page 78 | Page | e 80 |
|--|---|---|-------|
| 1 | A. There were some sections we wrote | 1 A. Well, I got to know him better when | C 60 |
| | together. There were some sections that | 2 I came to Boston University. I, obviously, have | |
| 1 | Dr. Rothman took the lead on. There were some | 3 known of him and I believe I had met him once. I | ī |
| | sessions that I took the lead on. | 4 met him at scientific meetings. And he was a very | |
| 5 | Q. Which sections did you take the lead | 5 close friend and colleague of my mentor at the | j |
| | on and which sections did Dr. Rothman take the | 6 University of Washington, Dr. Noel Weiss, who I | i |
| | lead on? | 7 coauthored one of my papers with. | |
| 8 | A. Dr. Rothman clarified the | 8 Q. Do you know Dr. Rothman socially as | |
| " | methodologic approach that we did, I wrote the | 9 well as professionally? | |
| 1 | initial drafts of the reviews of most of the | 10 A. Now I do. | |
| - | scientific literature that is documented in there, | | |
| 1 | and then together we wrote the Executive Summary | 11 Q. Have you read all of his 12 publications? | |
| 1 | - | 1 | |
| l . | and I believe our concluding thoughts. | 13 A. What, 600 or so? (Laugh). No, I 14 can't believe I don't believe I've read all of | |
| 14 | But it was an iterative process | | |
| | where we were back and forth on modifying each | 15 him, but I've read certainly the seminal | |
| | other's sections that we had initially written. | 16 publications that he's written. | |
| 17 | Q. So did you and Dr. Rothman write | 17 Q. Have you read any of his textbooks? | |
| | initial sections separate and then combine them? | 18 A. I use his textbook. | |
| 19 | A. We would write our sections and we | 19 Q. Which textbook do you use? | |
| 1 | would discuss it. And as I indicated on my | 20 A. "Modern Epidemiology." | |
| 1 | invoices, when we were meeting, we would be | Q. Are all the hours you have spent | |
| 1 | modifying our sections based on joint input on the | 22 working on this litigation reflected in the | |
| | appropriate wording to be used. | 23 invoices we marked as an exhibit and then what ye | ou |
| 24 | Q. Do the invoices we looked at reflect | 24 told me what you have done since that time? | |
| 1 | P 70 | Dage | |
| | Page 79 | | e 81 |
| 1 | the hours that you spent with Dr. Rothman in | 1 A. That's correct. | e 81 |
| 2 | the hours that you spent with Dr. Rothman in preparing this report? | A. That's correct. Q. Have you done any other work on this | e 81 |
| 3 | the hours that you spent with Dr. Rothman in preparing this report? A. I believe it does. | 1 A. That's correct. 2 Q. Have you done any other work on this 3 litigation that's not reflected in your invoices | e 81 |
| 2 3 4 | the hours that you spent with Dr. Rothman in preparing this report? A. I believe it does. Q. Does it show all the hours that you | A. That's correct. Q. Have you done any other work on this litigation that's not reflected in your invoices or what you told me about so far today? | e 81 |
| 2 3 4 5 | the hours that you spent with Dr. Rothman in preparing this report? A. I believe it does. Q. Does it show all the hours that you spent with Dr. Rothman in writing your report? | A. That's correct. Q. Have you done any other work on this litigation that's not reflected in your invoices or what you told me about so far today? A. No. | ge 81 |
| 2 3 4 5 6 | the hours that you spent with Dr. Rothman in preparing this report? A. I believe it does. Q. Does it show all the hours that you spent with Dr. Rothman in writing your report? A. Yes. | A. That's correct. Q. Have you done any other work on this litigation that's not reflected in your invoices or what you told me about so far today? A. No. Q. Looking at your report over on page | ge 81 |
| 2 3 4 5 6 7 | the hours that you spent with Dr. Rothman in preparing this report? A. I believe it does. Q. Does it show all the hours that you spent with Dr. Rothman in writing your report? A. Yes. Q. Does it also reflect all the hours | 1 A. That's correct. 2 Q. Have you done any other work on this 3 litigation that's not reflected in your invoices 4 or what you told me about so far today? 5 A. No. 6 Q. Looking at your report over on page 7 20, you state at the bottom that: | e 81 |
| 2 3 4 5 6 7 | the hours that you spent with Dr. Rothman in preparing this report? A. I believe it does. Q. Does it show all the hours that you spent with Dr. Rothman in writing your report? A. Yes. Q. Does it also reflect all the hours you spent working on your report? | 1 A. That's correct. 2 Q. Have you done any other work on this 3 litigation that's not reflected in your invoices 4 or what you told me about so far today? 5 A. No. 6 Q. Looking at your report over on page 7 20, you state at the bottom that: 8 "It is our opinion that talcum | |
| 2 3 4 5 6 7 8 9 | the hours that you spent with Dr. Rothman in preparing this report? A. I believe it does. Q. Does it show all the hours that you spent with Dr. Rothman in writing your report? A. Yes. Q. Does it also reflect all the hours you spent working on your report? A. I believe it does. | 1 A. That's correct. 2 Q. Have you done any other work on this 3 litigation that's not reflected in your invoices 4 or what you told me about so far today? 5 A. No. 6 Q. Looking at your report over on page 7 20, you state at the bottom that: 8 "It is our opinion that talcum 9 powder products, including Johnson's Baby Powd | ler |
| 2 3 4 5 6 7 8 9 10 | the hours that you spent with Dr. Rothman in preparing this report? A. I believe it does. Q. Does it show all the hours that you spent with Dr. Rothman in writing your report? A. Yes. Q. Does it also reflect all the hours you spent working on your report? A. I believe it does. Q. In the process of preparing your | 1 A. That's correct. 2 Q. Have you done any other work on this 3 litigation that's not reflected in your invoices 4 or what you told me about so far today? 5 A. No. 6 Q. Looking at your report over on page 7 20, you state at the bottom that: 8 "It is our opinion that talcum 9 powder products, including Johnson's Baby Powd 10 and Shower to Shower, applied to the genital area | ler |
| 2 3 4 5 6 7 8 9 10 11 | the hours that you spent with Dr. Rothman in preparing this report? A. I believe it does. Q. Does it show all the hours that you spent with Dr. Rothman in writing your report? A. Yes. Q. Does it also reflect all the hours you spent working on your report? A. I believe it does. Q. In the process of preparing your report, did you communicate with Dr. Rothman by | 1 A. That's correct. 2 Q. Have you done any other work on this 3 litigation that's not reflected in your invoices 4 or what you told me about so far today? 5 A. No. 6 Q. Looking at your report over on page 7 20, you state at the bottom that: 8 "It is our opinion that talcum 9 powder products, including Johnson's Baby Powd 10 and Shower to Shower, applied to the genital area 11 of women, can cause ovarian cancer." | ler |
| 2 3 4 5 6 7 8 9 10 11 | the hours that you spent with Dr. Rothman in preparing this report? A. I believe it does. Q. Does it show all the hours that you spent with Dr. Rothman in writing your report? A. Yes. Q. Does it also reflect all the hours you spent working on your report? A. I believe it does. Q. In the process of preparing your | 1 A. That's correct. 2 Q. Have you done any other work on this 3 litigation that's not reflected in your invoices 4 or what you told me about so far today? 5 A. No. 6 Q. Looking at your report over on page 7 20, you state at the bottom that: 8 "It is our opinion that talcum 9 powder products, including Johnson's Baby Powd 10 and Shower to Shower, applied to the genital area | ler |
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| 2 3 4 5 6 7 8 9 10 11 12 13 14 | the hours that you spent with Dr. Rothman in preparing this report? A. I believe it does. Q. Does it show all the hours that you spent with Dr. Rothman in writing your report? A. Yes. Q. Does it also reflect all the hours you spent working on your report? A. I believe it does. Q. In the process of preparing your report, did you communicate with Dr. Rothman by e-mail? | 1 A. That's correct. 2 Q. Have you done any other work on this 3 litigation that's not reflected in your invoices 4 or what you told me about so far today? 5 A. No. 6 Q. Looking at your report over on page 7 20, you state at the bottom that: 8 "It is our opinion that talcum 9 powder products, including Johnson's Baby Powd 10 and Shower to Shower, applied to the genital area 11 of women, can cause ovarian cancer." 12 Do you see where I'm reading? | ler |
| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 | the hours that you spent with Dr. Rothman in preparing this report? A. I believe it does. Q. Does it show all the hours that you spent with Dr. Rothman in writing your report? A. Yes. Q. Does it also reflect all the hours you spent working on your report? A. I believe it does. Q. In the process of preparing your report, did you communicate with Dr. Rothman by e-mail? A. Yes. | 1 A. That's correct. 2 Q. Have you done any other work on this 3 litigation that's not reflected in your invoices 4 or what you told me about so far today? 5 A. No. 6 Q. Looking at your report over on page 7 20, you state at the bottom that: 8 "It is our opinion that talcum 9 powder products, including Johnson's Baby Powd 10 and Shower to Shower, applied to the genital area 11 of women, can cause ovarian cancer." 12 Do you see where I'm reading? 13 A. Yes, I do. 14 Q. Does your opinion apply to corn 15 starch products? | ler |
| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 | the hours that you spent with Dr. Rothman in preparing this report? A. I believe it does. Q. Does it show all the hours that you spent with Dr. Rothman in writing your report? A. Yes. Q. Does it also reflect all the hours you spent working on your report? A. I believe it does. Q. In the process of preparing your report, did you communicate with Dr. Rothman by e-mail? A. Yes. Q. Do you still have those e-mails? A. No. Q. With regard to the final report, did | 1 A. That's correct. 2 Q. Have you done any other work on this 3 litigation that's not reflected in your invoices 4 or what you told me about so far today? 5 A. No. 6 Q. Looking at your report over on page 7 20, you state at the bottom that: 8 "It is our opinion that talcum 9 powder products, including Johnson's Baby Powd 10 and Shower to Shower, applied to the genital area 11 of women, can cause ovarian cancer." 12 Do you see where I'm reading? 13 A. Yes, I do. 14 Q. Does your opinion apply to corn | ler |
| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 | the hours that you spent with Dr. Rothman in preparing this report? A. I believe it does. Q. Does it show all the hours that you spent with Dr. Rothman in writing your report? A. Yes. Q. Does it also reflect all the hours you spent working on your report? A. I believe it does. Q. In the process of preparing your report, did you communicate with Dr. Rothman by e-mail? A. Yes. Q. Do you still have those e-mails? A. No. | 1 A. That's correct. 2 Q. Have you done any other work on this 3 litigation that's not reflected in your invoices 4 or what you told me about so far today? 5 A. No. 6 Q. Looking at your report over on page 7 20, you state at the bottom that: 8 "It is our opinion that talcum 9 powder products, including Johnson's Baby Powd 10 and Shower to Shower, applied to the genital area 11 of women, can cause ovarian cancer." 12 Do you see where I'm reading? 13 A. Yes, I do. 14 Q. Does your opinion apply to corn 15 starch products? | ler |
| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 | the hours that you spent with Dr. Rothman in preparing this report? A. I believe it does. Q. Does it show all the hours that you spent with Dr. Rothman in writing your report? A. Yes. Q. Does it also reflect all the hours you spent working on your report? A. I believe it does. Q. In the process of preparing your report, did you communicate with Dr. Rothman by e-mail? A. Yes. Q. Do you still have those e-mails? A. No. Q. With regard to the final report, did you read and approve each statement in the report? A. Yes. | 1 A. That's correct. 2 Q. Have you done any other work on this 3 litigation that's not reflected in your invoices 4 or what you told me about so far today? 5 A. No. 6 Q. Looking at your report over on page 7 20, you state at the bottom that: 8 "It is our opinion that talcum 9 powder products, including Johnson's Baby Powd 10 and Shower to Shower, applied to the genital area 11 of women, can cause ovarian cancer." 12 Do you see where I'm reading? 13 A. Yes, I do. 14 Q. Does your opinion apply to corn 15 starch products? 16 A. No, it does not. 17 Q. Does your opinion apply to body 18 powders generally? | ler |
| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 | the hours that you spent with Dr. Rothman in preparing this report? A. I believe it does. Q. Does it show all the hours that you spent with Dr. Rothman in writing your report? A. Yes. Q. Does it also reflect all the hours you spent working on your report? A. I believe it does. Q. In the process of preparing your report, did you communicate with Dr. Rothman by e-mail? A. Yes. Q. Do you still have those e-mails? A. No. Q. With regard to the final report, did you read and approve each statement in the report? A. Yes. Q. Was there any disagreement on | 1 A. That's correct. 2 Q. Have you done any other work on this 3 litigation that's not reflected in your invoices 4 or what you told me about so far today? 5 A. No. 6 Q. Looking at your report over on page 7 20, you state at the bottom that: 8 "It is our opinion that talcum 9 powder products, including Johnson's Baby Powd 10 and Shower to Shower, applied to the genital area 11 of women, can cause ovarian cancer." 12 Do you see where I'm reading? 13 A. Yes, I do. 14 Q. Does your opinion apply to corn 15 starch products? 16 A. No, it does not. 17 Q. Does your opinion apply to body 18 powders generally? 19 A. Only to the extent that they include | ler |
| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 | the hours that you spent with Dr. Rothman in preparing this report? A. I believe it does. Q. Does it show all the hours that you spent with Dr. Rothman in writing your report? A. Yes. Q. Does it also reflect all the hours you spent working on your report? A. I believe it does. Q. In the process of preparing your report, did you communicate with Dr. Rothman by e-mail? A. Yes. Q. Do you still have those e-mails? A. No. Q. With regard to the final report, did you read and approve each statement in the report? A. Yes. Q. Was there any disagreement on statements as you were preparing the report? | 1 A. That's correct. 2 Q. Have you done any other work on this 3 litigation that's not reflected in your invoices 4 or what you told me about so far today? 5 A. No. 6 Q. Looking at your report over on page 7 20, you state at the bottom that: 8 "It is our opinion that talcum 9 powder products, including Johnson's Baby Powd 10 and Shower to Shower, applied to the genital area 11 of women, can cause ovarian cancer." 12 Do you see where I'm reading? 13 A. Yes, I do. 14 Q. Does your opinion apply to corn 15 starch products? 16 A. No, it does not. 17 Q. Does your opinion apply to body 18 powders generally? 19 A. Only to the extent that they include 20 talc. | ler |
| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 | the hours that you spent with Dr. Rothman in preparing this report? A. I believe it does. Q. Does it show all the hours that you spent with Dr. Rothman in writing your report? A. Yes. Q. Does it also reflect all the hours you spent working on your report? A. I believe it does. Q. In the process of preparing your report, did you communicate with Dr. Rothman by e-mail? A. Yes. Q. Do you still have those e-mails? A. No. Q. With regard to the final report, did you read and approve each statement in the report? A. Yes. Q. Was there any disagreement on | 1 A. That's correct. 2 Q. Have you done any other work on this 3 litigation that's not reflected in your invoices 4 or what you told me about so far today? 5 A. No. 6 Q. Looking at your report over on page 7 20, you state at the bottom that: 8 "It is our opinion that talcum 9 powder products, including Johnson's Baby Powd 10 and Shower to Shower, applied to the genital area 11 of women, can cause ovarian cancer." 12 Do you see where I'm reading? 13 A. Yes, I do. 14 Q. Does your opinion apply to corn 15 starch products? 16 A. No, it does not. 17 Q. Does your opinion apply to body 18 powders generally? 19 A. Only to the extent that they include | ler |
| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 | the hours that you spent with Dr. Rothman in preparing this report? A. I believe it does. Q. Does it show all the hours that you spent with Dr. Rothman in writing your report? A. Yes. Q. Does it also reflect all the hours you spent working on your report? A. I believe it does. Q. In the process of preparing your report, did you communicate with Dr. Rothman by e-mail? A. Yes. Q. Do you still have those e-mails? A. No. Q. With regard to the final report, did you read and approve each statement in the report? A. Yes. Q. Was there any disagreement on statements as you were preparing the report? | 1 A. That's correct. 2 Q. Have you done any other work on this 3 litigation that's not reflected in your invoices 4 or what you told me about so far today? 5 A. No. 6 Q. Looking at your report over on page 7 20, you state at the bottom that: 8 "It is our opinion that talcum 9 powder products, including Johnson's Baby Powd 10 and Shower to Shower, applied to the genital area 11 of women, can cause ovarian cancer." 12 Do you see where I'm reading? 13 A. Yes, I do. 14 Q. Does your opinion apply to corn 15 starch products? 16 A. No, it does not. 17 Q. Does your opinion apply to body 18 powders generally? 19 A. Only to the extent that they include 20 talc. 21 Q. With regard to the opinion statement 22 that I just read at the bottom of page 20 | ler |
| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 | the hours that you spent with Dr. Rothman in preparing this report? A. I believe it does. Q. Does it show all the hours that you spent with Dr. Rothman in writing your report? A. Yes. Q. Does it also reflect all the hours you spent working on your report? A. I believe it does. Q. In the process of preparing your report, did you communicate with Dr. Rothman by e-mail? A. Yes. Q. Do you still have those e-mails? A. No. Q. With regard to the final report, did you read and approve each statement in the report? A. Yes. Q. Was there any disagreement on statements as you were preparing the report? A. I wouldn't say we had disagreements. | 1 A. That's correct. 2 Q. Have you done any other work on this 3 litigation that's not reflected in your invoices 4 or what you told me about so far today? 5 A. No. 6 Q. Looking at your report over on page 7 20, you state at the bottom that: 8 "It is our opinion that talcum 9 powder products, including Johnson's Baby Powd 10 and Shower to Shower, applied to the genital area 11 of women, can cause ovarian cancer." 12 Do you see where I'm reading? 13 A. Yes, I do. 14 Q. Does your opinion apply to corn 15 starch products? 16 A. No, it does not. 17 Q. Does your opinion apply to body 18 powders generally? 19 A. Only to the extent that they include 20 talc. 21 Q. With regard to the opinion statement | ler |

| | Page 82 | | Page 84 |
|---|---|--|--|
| 1 | statement in any published peer-reviewed | 1 | |
| | publication, correct? | 2 | - |
| 3 | A. I have not. Not not the word | 3 | - |
| 4 | "cause." | 4 | |
| 5 | Q. You have never made the statement | 5 | that. |
| 6 | that I just read to you in anything you have | 6 | A. Yes. |
| | written before November 2023, correct? | 7 | Q. You note in this article that: |
| 8 | A. In any public statement, no. | 8 | "Despite this consistency, the |
| 9 | Q. Have you made this statement in | 9 | association is still viewed with skepticism based |
| 10 | anything other than this report since November | 10 | upon weak odds ratios, poor dose-response |
| 11 | 2023? | 11 | relationships and an incomplete understanding of |
| 12 | A. No. | 12 | the biological mechanism by which talc might lead |
| 13 | Q. On page 2 of your report | 13 | to ovarian cancer." |
| 14 | A. Uh-huh. | 14 | Do you see where I'm reading? |
| 15 | Q you identify your publications on | 15 | A. No, I'm not sure I do. |
| 16 | talc use and ovarian cancer, correct? | 16 | Q. (Indicates). |
| 17 | A. Yes. | 17 | A. Oh, oh, oh. It's not in the |
| 18 | Q. There are four published articles | 18 | abstract. |
| 19 | and one letter to the editor? | 19 | MR. TISI: It's not in the |
| 20 | A. Correct. | 20 | abstract. You said the abstract. |
| 21 | Q. Your last published peer-reviewed | 21 | BY MR. HEGARTY: |
| 1 | article was in 1999, 25 years ago, right? | 22 | Q. I said the paragraph below the |
| 23 | A. Yes, but I don't know to what extent | 23 | abstract. |
| 24 | the editors at JAMA peer review letters to the | 24 | A. Oh, I'm sorry. I'm sorry. |
| | Page 83 | | Page 85 |
| 1 | editor. | 1 | , |
| 2 | Q. Fair. | 2 | - · |
| 3 | You don't know one way or the other? | 3 | J 1 |
| 4 | A. I don't know one way or the other. | 4 | |
| 5 | Q. You do not state in any of your published articles that talc use can cause ovarian | 5 | O T1 |
| | nublished articles that falc use can cause ovarian | | |
| | • | 6 | "Despite this consistency, the |
| 7 | cancer, correct? | 6 7 | "Despite this consistency, the association is still viewed with skepticism |
| 7 8 | cancer, correct? A. I don't recall that I use that | 6 7 8 | "Despite this consistency, the association is still viewed with skepticism A. Yes. |
| 7 8 9 | cancer, correct? A. I don't recall that I use that particular term, but I would have to look and see | 6 7 8 . 9 | "Despite this consistency, the association is still viewed with skepticism A. Yes. Q based upon weak odds ratios, poor |
| 7 8 9 10 | cancer, correct? A. I don't recall that I use that particular term, but I would have to look and see Q. With regard to your 1999 | 6 7 8 . 9 10 | "Despite this consistency, the association is still viewed with skepticism A. Yes. Q based upon weak odds ratios, poor dose-response relationships and an incomplete |
| 7 8 9 10 11 | cancer, correct? A. I don't recall that I use that particular term, but I would have to look and see Q. With regard to your 1999 publication, I'm going to show that to you. | 6 7 8 . 9 10 11 | "Despite this consistency, the association is still viewed with skepticism A. Yes. Q based upon weak odds ratios, poor dose-response relationships and an incomplete understanding of biological mechanism by which |
| 7 8 9 10 11 12 | cancer, correct? A. I don't recall that I use that particular term, but I would have to look and see Q. With regard to your 1999 publication, I'm going to show that to you. A. Yes. | 6 7 8 . 9 10 11 12 | "Despite this consistency, the association is still viewed with skepticism A. Yes. Q based upon weak odds ratios, poor dose-response relationships and an incomplete understanding of biological mechanism by which talc might lead to ovarian cancer." |
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| | Page 86 | | Page 88 |
|---|---|---|---|
| 1 | talc exposure in these studies is based on | 1 | dose response. |
| | personal recollection." | | BY MR. HEGARTY: |
| 3 | That's a true statement, correct? | 3 | Q. What I read to you was a true |
| 4 | A. Except that if you look at the | | statement as of the time you published this |
| | sentence following that, it seems that recall bias | | article, correct? |
| 1 | seems more likely to affect exposures that have | 6 | A. Yes. |
| 1 | occurred over a short period of time. | 7 | Q. IARC published its monograph |
| 8 | Q. As far as the sentence I just read | 8 | regarding talc use |
| 9 | to you, though, you stand by that sentence, | 9 | MR. TISI: Are you done with |
| | correct? | 10 | this? |
| 11 | A. I stand by recall bias is a possible | 11 | MR. HEGARTY: I'm done with it |
| 12 | could have a possible effect in those who have | 12 | for now. |
| 13 | used it sporadically over their lifetime. | 13 | MR. TISI: Okay. |
| 14 | Q. But in terms of all the statements | 14 | BY MR. HEGARTY: |
| 15 | in this article, you still stand by them, correct? | 15 | Q. IARC published its monograph |
| 16 | A. Yes, I believe so. I mean, yes, I | 16 | regarding talc use and ovarian cancer in 2010 |
| 17 | stand by everything I've written. | 17 | where it designated talc as to be possibly |
| 18 | Q. Please turn over to page 355. | 18 | carcinogenic. |
| 19 | A. Uh-huh. | 19 | Did you read that monograph when it |
| 20 | Q. Left-hand side, end of the paragraph | | came out? |
| | end of the left-hand side. | 21 | A. I can't say that I read it when it |
| 22 | MR. TISI: Let me get there, | | came out. |
| 23 | Mark. | 23 | Q. Do you recall when it was when you |
| 24 | BY MR. HEGARTY: | 24 | did read that IARC Monograph, if you did? |
| | Page 87 | | Page 89 |
| 1 | Q. That paragraph reads: | 1 | A. I looked at that monograph and other |
| 2 | "The most obvious weakness in the | | IARC statements during the process of reviewing |
| | argument for biologic credibility of the talc and | | the evidence. |
| | ovarian cancer association is the lack of a clear | 4 | Q. "During the process of reviewing the evidence." |
| | dose response. Most talc and ovarian cancer studies that have addressed dose response, | 6 | Are you talking about during the |
| | including this one, have failed to demonstrate | | process of reviewing the evidence in connection |
| | consistent dose response relationships with | | |
| | | Q | - |
| | | | with preparing your expert report? |
| 9 | measures of the intensity of the exposure, | 9 | with preparing your expert report? A. Yes. |
| 9 10 | measures of the intensity of the exposure, especially when the trend is examined among users | 9 10 | with preparing your expert report? A. Yes. Q. Prior to you starting to work on |
| 9 10 11 | measures of the intensity of the exposure, especially when the trend is examined among users only." | 9 10 11 | with preparing your expert report? A. Yes. Q. Prior to you starting to work on your expert report, had you ever reviewed the 2010 |
| 9 10 11 12 | measures of the intensity of the exposure, especially when the trend is examined among users only." Do you stand by that statement? | 9 10 11 | with preparing your expert report? A. Yes. Q. Prior to you starting to work on your expert report, had you ever reviewed the 2010 IARC Monograph on talc? |
| 9 10 11 | measures of the intensity of the exposure, especially when the trend is examined among users only." | 9 10 11 12 | with preparing your expert report? A. Yes. Q. Prior to you starting to work on your expert report, had you ever reviewed the 2010 IARC Monograph on talc? |
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| 1 | Page 90 opinion that you've said in your report that talc | 1 | Page 92 A. I believed in the research that I |
|--|---|--|--|
| | applied to the genital area can cause ovarian | | had done and the associations that I observed as |
| | cancer, did you come to that opinion prior to | 3 | being as not being explained by biases to my - |
| | being contacted by plaintiffs' counsel about | | based on my evaluation. |
| | - · · · · | | • |
| 1 - | serving as an expert witness in this litigation? A. I believe in my in my 1992 | 5 6 | I certainly yeah. O. Go ahead. |
| 6 | ž ž | 7 | |
| 7 | · · · · · · · · · · · · · · · · · · · | | Have you reviewed the transcript of the proceedings? |
| | that about 10 percent of the incidence of ovarian | 8 9 | 1 6 |
| | cancer could be or was attributable to talc | 10 | A. I have. I have. |
| | exposure. | | Q. When did you review the transcript |
| 11 | Q. My question still is a little | | of the proceedings? |
| | different than what you're answering. | 12 | A. Recently, actually. |
| 13 | You just you told me about what | 13 | MR. HEGARTY: I'm going to |
| | you believed as to the association being a true | 14 | mark as the next exhibit, Exhibit |
| | association. You told me what you wrote in you | | Number 7, the transcript of the FDA |
| | 1992 article about 10 percent of cases | 16 | 1 1 |
| | involving | 17 | (Document marked for |
| 18 | A. 10 percent of the incidence. | 18 | identification as Harlow Exhibit 7.) |
| 19 | Q. 10 percent of the incidence. | 19 | THE WITNESS: Yep. |
| 20 | 3 1 1 3 | | BY MR. HEGARTY: |
| | the causal statement you made in your expert | 21 | Q. Is the transcript that I marked as |
| | report. | | Exhibit Number 7 what you reviewed recently? |
| 23 | When did you come to that causal | 23 | A. Yes. |
| 24 | opinion? | 24 | Q. Please turn over to page 272. They |
| | P 01 | | |
| _ | Page 91 | | Page 93 |
| 1 | A. I came to that causal opinion in | | are numbered at the top. |
| 2 | A. I came to that causal opinion in doing this report. | 2 | are numbered at the top. A. Yep. |
| 2 3 | A. I came to that causal opinion in doing this report.Q. Now, as you mentioned a short time | 2 3 | are numbered at the top. A. Yep. I'm going to take the clip off. If |
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| Page 94 | Page 96 |
|---|--|
| 1 The next document I'm going to | 1 That was a statement made at the |
| 2 show you, which I'm marking as Exhibit | 2 conference. |
| 3 Number 8, is the publication by Carr that | 3 Are you aware of that? |
| 4 came out of that FDA workshop. | 4 A. I'm not aware of that. |
| 5 (Document marked for | 5 Q. Turn over to page 215, the next |
| 6 identification as Harlow Exhibit 8.) | 6 page. |
| 7 BY MR. HEGARTY: | 7 A. Uh-huh. |
| 8 Q. Have you seen the publication I | 8 Q. Look at the very bottom of the |
| 9 marked as Exhibit Number 8 before today? | 9 left-hand column carrying over to the right-hand |
| 10 A. Oh, yes. | 10 column. |
| 11 Q. And did you review that recently? | 11 A. Uh-huh. |
| 12 A. Yes. | 12 Q. The sentence at the very bottom |
| 13 Q. It shows on page 2 that you were a | 13 reads: |
| 14 participant? | 14 "Following the many issues raised by |
| 15 A. That's correct. | 15 all presenters, the ensuing discussion generally |
| 16 Q. Please turn to page 214 of the Carr | 16 agreed that while some weak association between |
| 17 paper. | 17 talc exposure and ovarian tumors has been |
| First of all, before we go there. | 18 reported, it was not sufficient warning for |
| Did you review the Carr paper when | 19 concern." |
| 20 it came out back in 1995? | First of all, did I read it |
| 21 A. I did not I don't recall. I did | 21 correctly? |
| 22 not I was not involved in the preparation or | A. You did read it correctly. |
| 23 review of this. I might have seen it before it | Q. Do you dispute that statement? |
| 24 came in print. I just I don't recall. | 24 A. Yes, I do. |
| Page 95 | Page 97 |
| 1 Q. Had you read it in some context | 1 Q. Back when you reviewed Carr, did you |
| 2 prior to being contacted by plaintiffs' counsel in | 2 write a letter to the editor or contact the |
| 3 this litigation? | 3 authors let me start over again. |
| 4 A. Oh, prior to this litigation? | Back when you reviewed the Carr |
| 5 Q. Yes, sir. | 5 study back in the 1990s, did you contact Carr or |
| 6 A. I'm sure I did back in the '90s, but | 6 any of those involved in this publication and |
| 7 not since then. | 7 express concern about any of the language used in |
| 8 Q. And in looking at page 214 | 8 the article? |
| 9 A. Yes. | 9 A. No. |
| 10 Q in the lower right-hand corner, | 10 MR. TISI: Objection. Wait. |
| 11 if you look sort of in the middle of that very | 11 Let me place an objection to the 12 characterization of this article as a |
| 12 last paragraph, the sentence beginning "To | |
| 13 reasonable people." 14 Do you see that sentence? | 13 study. It's not a study. |
| | 14 You may answer. 15 THE WITNESS: No. Instead I |
| 1 0 1 | 15 THE WITNESS: No. Instead, I |
| | wrote an entire review article that was |
| , 8 | published in that issue, which summarized |
| · | 18 what we had presented at the conference.19 BY MR. HEGARTY: |
| | |
| 1 1 | 20 Q. Have you ever in any published |
| 21 with reasonable concern for prudence these | 21 any publication of yours specifically addressed |
| 22 clues suggest that the probability of human risk23 is likely nonexistent under customary conditions | 22 any of the statements in the Carr article?23 A. No. |
| 24 of use." | |
| 27 of use. | Q. Have you publicly in any forum, |

| | Page 98 | | Page 100 |
|--|--|--|---|
| 1 1 | whether published or otherwise, taken issue with | 1 | Q. Does he stand by what he wrote back |
| | any of the statements contained in the Carr | | in 2000? |
| | article, including the statements I read to you? | 3 | A. He stands by what he signed his name |
| 4 | A. No, not in any public no, not | 4 | to in the report that we wrote together. |
| 5 1 | publicly at all. | 5 | Q. My question, though, is: Does he |
| 6 | MR. HEGARTY: You can put that | 6 | stand by, from what he has told you, what I marked |
| 7 | document aside for the moment. | | as Exhibit Number 9? |
| 8 | The next document I want to | 8 | MS. PARFITT: Objection. |
| 9 | talk to you about, which I'll mark as | 9 | THE WITNESS: I have no idea |
| 10 | Exhibit Number 9, is Dr. Rothman et al.'s | 10 | whether he does or not. |
| 11 | document "Interpretation of Epidemiologic | 11 | BY MR. HEGARTY: |
| 12 | Studies on Talc and Ovarian Cancer." | 12 | Q. Turning to page 2, in the |
| 13 | (Document marked for | 13 | "Introduction" section, Dr. Rothman wrote that he |
| 14 | identification as Harlow Exhibit 9.) | | analyzed 23 case-control studies involving talc |
| 15 | THE WITNESS: Uh-huh. | | and ovarian cancer. |
| 16 | MR. TISI: Are you talking | 16 | These included your studies as well, |
| 17 | about | 17 | correct? |
| 18 | MR. HEGARTY: The one I just | 18 | A. Uh-huh. |
| 19 | handed to you. | 19 | Q. Yes, sir? |
| 20 | MR. TISI: Okay. | 20 | A. Yes. |
| 21 | THE WITNESS: Uh-huh. | 21 | MR. TISI: Say "yes." |
| | BY MR. HEGARTY: | 22 | THE WITNESS: I'm sorry. |
| 23 | Q. When did you first see Exhibit | 23 | Yes. |
| | Number 9? | | BY MR. HEGARTY: |
| | | | |
| | D 00 | | P 101 |
| 1 | Page 99 A I first saw it after I had started | 1 | Page 101 O The "Introduction" section above |
| 1 | A. I first saw it after I had started | 1 2 | Q. The "Introduction" section above |
| 2 0 | A. I first saw it after I had started doing work in preparation for our report that | 2 | Q. The "Introduction" section above Figure 1, just above Figure 1 |
| 2 d 3 I | A. I first saw it after I had started doing work in preparation for our report that Dr. Rothman and I did. | 2 3 | Q. The "Introduction" section above Figure 1, just above Figure 1 A. Yes. |
| 2 d 3 I 4 | A. I first saw it after I had started doing work in preparation for our report that Dr. Rothman and I did. Q. The conclusion of this analysis is | 2 3 4 | Q. The "Introduction" section above Figure 1, just above Figure 1 A. Yes. Q states or notes that the relative |
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| 2 G 3 I 4 5 s 6 | A. I first saw it after I had started doing work in preparation for our report that Dr. Rothman and I did. Q. The conclusion of this analysis is set on page 1. A. Yes. | 2 3 4 5 6 | Q. The "Introduction" section above Figure 1, just above Figure 1 A. Yes. Q states or notes that the relative risk concluded from that review is 1.31. That is characterized or called as a "slight positive |
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| | Page 102 | | Page 104 |
|----|---|----------|---|
| 1 | BY MR. HEGARTY: | 1 | You actually refer to the 1.31 |
| 2 | Q. Let me ask in a different way. | _ | finding from Dr. Rothman's 2000 study, correct? |
| 3 | Do you state anywhere in your report | 3 | A. That's correct. |
| | that the relative risks or odds ratios reported | 4 | Q. And you actually show |
| | for talc use and ovarian cancer are strong? | 5 | A. And we cite it. |
| 6 | A. I don't believe we used "strong" as | 6 | Q. And you cite to it? |
| 7 | a word. I believe we used "consistently seen" | 7 | A. Yes. |
| | across multiple studies and | 8 | Q. You show Figure 1 from the 2000 |
| 9 | Q. Did you I'm sorry. Go ahead. | 9 | _ |
| 10 | A and meta-analyses show a | 10 | A. That's correct. |
| 11 | consistent association with narrow confidence | 11 | Q. You note at the bottom of page 7 |
| 12 | intervals. | 12 | that: |
| 13 | Q. Is it your opinion in this | 13 | As regards to the 1.31 estimated |
| 14 | litigation that the relative risks and odds ratios | 14 | risk ratio that if valid, it would apply a 31 |
| 15 | that are reported for talc use and ovarian cancer | 15 | percent greater risk of ovarian cancer among tale |
| 16 | are strong? | 16 | users. |
| 17 | MR. TISI: Objection. | 17 | Correct? |
| 18 | THE WITNESS: Yeah. I would | 18 | A. That's correct. |
| 19 | say they are clinically relevant and | 19 | Q. Now, Dr. Rothman in this, in his |
| 20 | important. | 20 | analysis in Exhibit Number 9 |
| 21 | BY MR. HEGARTY: | 21 | A. Yes. |
| 22 | Q. Have you ever characterized in any | 22 | Q his 2000 analysis, did not |
| | publication of yours relative risks in the range | 23 | believe it was valid, correct? |
| 24 | of 1.2, 1.3, 1.4 as weak? | 24 | MR. TISI: Objection. |
| | Page 103 | | Page 105 |
| 1 | A. I'm sure I have. | 1 | THE WITNESS: I don't know |
| 2 | Q. In fact, we looked at your 1999 | 2 | whether he believed it was valid or not. |
| | publication where you characterized the reported | | He well, I'm looking for where he |
| | relative risks at the time as weak odds ratios, | 4 | might have where he specifically said |
| 5 | correct? | 5 | that. |
| 6 | A. That's correct. | | BY MR. HEGARTY: |
| 7 | Q. Back in 1999, based on the odds | 7 | Q. Well, based on the conclusion |
| 1 | ratios you had reviewed at the time, you | 8 | A. Yeah. |
| 9 | considered those to be weak odds ratios, correct? | | Q at the bottom of the Executive |
| 10 | MR. TISI: Objection. | | Summary, wouldn't you agree that he did not |
| 11 | THE WITNESS: No. Well, weak | 11 | |
| 12 | odds ratios merely means that it | 12 | MR. TISI: Objection. |
| 13 | doesn't mean that it's clinically | | BY MR. HEGARTY: |
| 14 | important. It means that it's not 3.0, | 14 | Q or risk ratio let me finish my |
| 15 | 4.0, 5.0. It happened to be around 1.3, | | question risk ratio was valid? |
| 16 | 1.4. | 16 | MR. TISI: Object. Let me |
| | BY MR. HEGARTY: | 17 | just object. |
| 18 | Q. Looking at page 2 of your report. | 18 | You referred to the Executive |
| 19 | A. Of my report? | 19 | Summary as a conclusion. As you know, |
| 20 | Q. Of your report. | 20 | counsel, there is actually a Conclusion |
| 21 | I'm sorry. It is it is page 7. | 21 | in the report that is not the Executive |
| 22 | A. Yes. | 22 | Summary. |
| 1 | | | |
| 23 | Q. You state at the bottom or, first of all, before I go there. | 23 24 | So if you want him to look at the Conclusion, |

| Page 106 1 but don't characterize the Executive | Page 108 1 MR. TISI: Objection. |
|---|--|
| 2 Summary as a conclusion. | 2 BY MR. HEGARTY: |
| 3 BY MR. HEGARTY: | 3 Q. You would not have wrote you |
| 4 Q. You can answer. | 4 would not have authored the statements contained |
| 5 A. I guess I would agree with counsel | 5 in Dr. Rothman's 2000 report? |
| 6 that his ultimate opinion came in the summary of | _ |
| 7 the of the report. | 7 that he specifically stated that there was no |
| 8 Q. Well, the conclusion | 8 biological plausibly plausible explanation for |
| 9 A. Let's look at that. | 9 it, and there was ample evidence at that time of |
| 10 Q on page 8, the very bottom it | 10 this report. |
| 11 says: | 11 Q. Did Dr. Rothman tell you what he |
| "Based on these considerations" | 12 thought had changed since 2000 |
| 13 referring to what he described above again, | 13 A. No. |
| 14 this is page 8. | 14 Q that would change his opinions? |
| 15 A. Oh, page 8. | 15 A. No. |
| 16 Q. The "Conclusion" section. | 16 Q. If you look over on page 3? |
| 17 A. Yeah. Hold on. Yes. Uh-huh. | 17 A. Of his report? |
| 18 Q. He writes: | 18 Q. Of his 2000 publication. |
| 19 "Based on these considerations, we | 19 A. 2000 report. Okay. Hold on. |
| 20 suggest that the evidence to date does not | 20 MR. TISI: Objection to |
| 21 indicate that talc can be 'reasonably anticipated | 21 calling it a publication. |
| 22 to be a human carcinogen." | 22 THE WITNESS: Okay. |
| 23 Correct? | 23 BY MR. HEGARTY: |
| MR. TISI: Please, you're free | 24 Q. Look under the section "Issues |
| Page 107 | Page 109 |
| 1 to read the entire Conclusion. | 1 Affecting Causal Inference" section. |
| THE WITNESS: Yeah, yeah. | 2 Do you see that? |
| 3 (Reviews document.) | 3 A. Yes. |
| 4 Yes, he states that. | 4 Q. This describes a methodology |
| 5 BY MR. HEGARTY: | 5 Dr. Rothman performed back in 2000, correct? |
| 6 Q. So do you disagree that Dr. Rothman | 6 A. Yes. |
| 7 back in 2000 did not find valid that the that | 7 Q. As to dose |
| 8 there was a 31 percent greater risk for ovarian | 8 MR. TISI: Actually, if you're |
| 9 cancer among talc users? | 9 going to refer to the section and ask you |
| MR. TISI: Objection. | about the methodology, please read it, |
| 11 THE WITNESS: I believe | 11 sir. |
| MR. TISI: That misstates | THE WITNESS: Yeah, yeah. |
| 13 states what he said. | 13 BY MR. HEGARTY: |
| 14 Go ahead. | 14 Q. As to dose response |
| 15 BY MR. HEGARTY: | MR. TISI: Give him a chance |
| 16 Q. You can answer. | 16 to read it, Mark. |
| 17 A. Well, I believe that's what he | 17 MR. HEGARTY: Okay, but he |
| 18 thought at the time. Obviously, given that he | 18 didn't ask he needed to read it. 19 THE WITNESS: No, I don't. |
| 19 coauthored my report, he does not believe that 20 now. | 20 You can ask the question. |
| | 1 |
| Q. When you read the 2000 summary, did 22 you agree that it was accurate at the time it was | the question, but he does need to read it |
| 22 you agree that it was accurate at the time it was 23 prepared? | if you want to ask him about the |
| | |
| 24 A. No. | 24 methodology. |

| | Page 110 | | Page 112 |
|--|--|--|--|
| 1 | MR. HEGARTY: Chris, I think | 1 | Q. Where in your report do you report |
| 2 | the doctor needs to tell me if he needs | 2 | exposure misclassification? |
| 3 | to read it first. Please don't instruct | 3 | A. In the review of the cohort studies. |
| 4 | him to read it. | 4 | Q. Nowhere in your report do you do an |
| 5 | MR. TISI: I'm objecting. I'm | 5 | |
| 6 | going to instruct him. If you're going | 6 | A. That's not true. |
| 7 | to ask him about a section of the report, | 7 | Q. Show me in your report where you do |
| 8 | he needs to take a look at it. | 8 | |
| 9 | MR. HEGARTY: Understood, | 9 | A. By we discuss the potential for |
| 10 | but and I'm fine with that. | | confounding. I'm not sure what you mean by "as |
| 11 | MR. TISI: Thank you. | | analysis of confounding." |
| 12 | MR. HEGARTY: But if he needs | 12 | Q. Well, where do you discuss the |
| 13 | to read it, he needs to tell me so we can | 1 | potential for confounding in your report? |
| 14 | go off the record so I'm not taking up | 14 | A. My report? |
| 15 | time with him reading. | 15 | (Reviews document.) |
| 16 | MR. TISI: Well, I'm not going | 16 | |
| 17 | to go off the record. If you're going to | 1 | methodological review. |
| 18 | ask him about a section of the report, | 18 | Q. On what page? |
| 19 | he's going to read the section of the | 19 | A. On page 4. The paragraph that |
| 20 | | 1 | begins: |
| 21 | report. MR. HEGARTY: Fine. | 21 | "If no checklist for causal |
| 22 | MR. TISI: If you ask him | 1 | inference exists, then how does causal inference |
| 23 | about a sentence, that's fine, but go | | proceed?" |
| 24 | about a sentence, that's thie, but go ahead. | 24 | And then the sentence was: |
| 24 | | 24 | |
| 1 | Page 111 BY MR. HEGARTY: | 1 | Page 113 "Or, was the association |
| 2 | Q. Are you there | _ | attributable to some other factor that causes the |
| 3 | A. Yes. | 1 | disease and is associated with the exposure unde |
| 4 | Q with me? | | study?" |
| 5 | A. Please ask your question. | 5 | That is the definition of |
| 6 | Q. Dr. Rothman writes in that section | - | That is the definition of |
| | O. Di. Koumian writes in that section | - 6 | confounding |
| ′ 7 | • | | confounding. |
| | as it relates to dose response: | 7 | Q. Do you do analysis of potential |
| 8 | as it relates to dose response: "With rare exception, every causal | 7 8 | Q. Do you do analysis of potential confounding factors with regard to talc and |
| 8 9 | as it relates to dose response: "With rare exception, every causal relation in epidemiologic research shows a | 7 8 9 | Q. Do you do analysis of potential confounding factors with regard to talc and ovarian cancer in your report? |
| 8 9 10 | as it relates to dose response: "With rare exception, every causal relation in epidemiologic research shows a progressive relation between various measures o | 7 8 9 f10 | Q. Do you do analysis of potential confounding factors with regard to talc and ovarian cancer in your report? A. In the evaluation of the articles, |
| 8 9 10 11 | as it relates to dose response: "With rare exception, every causal relation in epidemiologic research shows a progressive relation between various measures o increasing exposure." | 7 8 9 f10 11 | Q. Do you do analysis of potential confounding factors with regard to talc and ovarian cancer in your report? A. In the evaluation of the articles, we looked to see whether confounders were taken |
| 8 9 10 11 12 | as it relates to dose response: "With rare exception, every causal relation in epidemiologic research shows a progressive relation between various measures o increasing exposure." A. Uh-huh. | 7 8 9 f10 11 12 | Q. Do you do analysis of potential confounding factors with regard to talc and ovarian cancer in your report? A. In the evaluation of the articles, we looked to see whether confounders were take into consideration in the assessments. |
| 8 9 10 11 12 13 | as it relates to dose response: "With rare exception, every causal relation in epidemiologic research shows a progressive relation between various measures o increasing exposure." A. Uh-huh. Q. That is a true statement, correct? | 7 8 9 f10 11 12 13 | Q. Do you do analysis of potential confounding factors with regard to talc and ovarian cancer in your report? A. In the evaluation of the articles, we looked to see whether confounders were take into consideration in the assessments. Q. Nowhere in your report do you |
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| 8 9 10 11 12 13 14 15 16 17 18 19 20 21 | as it relates to dose response: "With rare exception, every causal relation in epidemiologic research shows a progressive relation between various measures o increasing exposure." A. Uh-huh. Q. That is a true statement, correct? MR. TISI: Objection. THE WITNESS: Yes. BY MR. HEGARTY: Q. His methodology then lists five factors: exposure misclassification, recall bias, confounding, dose-response trends, and biologic mechanism, correct? A. Yes. | 7 8 9 f10 11 12 13 14 15 16 17 18 19 20 21 | Q. Do you do analysis of potential confounding factors with regard to talc and ovarian cancer in your report? A. In the evaluation of the articles, we looked to see whether confounders were take into consideration in the assessments. Q. Nowhere in your report do you discuss the potential confounding factor of BMI correct? A. Not not that I'm aware of. But, remember, a confounder has to have preceded the use of a particular exposure. Q. Nowhere in your report do you discuss the potential confounder of hormone replacement therapy, correct? |
| 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 | as it relates to dose response: "With rare exception, every causal relation in epidemiologic research shows a progressive relation between various measures o increasing exposure." A. Uh-huh. Q. That is a true statement, correct? MR. TISI: Objection. THE WITNESS: Yes. BY MR. HEGARTY: Q. His methodology then lists five factors: exposure misclassification, recall bias, confounding, dose-response trends, and biologic mechanism, correct? A. Yes. Q. Nowhere in your report do you | 7 8 9 f10 11 12 13 14 15 16 17 18 19 20 21 22 | Q. Do you do analysis of potential confounding factors with regard to talc and ovarian cancer in your report? A. In the evaluation of the articles, we looked to see whether confounders were take into consideration in the assessments. Q. Nowhere in your report do you discuss the potential confounding factor of BMI correct? A. Not not that I'm aware of. But, remember, a confounder has to have preceded the use of a particular exposure. Q. Nowhere in your report do you discuss the potential confounder of hormone replacement therapy, correct? A. Again, it's not considered a |
| 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 | as it relates to dose response: "With rare exception, every causal relation in epidemiologic research shows a progressive relation between various measures o increasing exposure." A. Uh-huh. Q. That is a true statement, correct? MR. TISI: Objection. THE WITNESS: Yes. BY MR. HEGARTY: Q. His methodology then lists five factors: exposure misclassification, recall bias, confounding, dose-response trends, and biologic mechanism, correct? A. Yes. | 7 8 9 f10 11 12 13 14 15 16 17 18 19 20 21 22 23 | Q. Do you do analysis of potential confounding factors with regard to talc and ovarian cancer in your report? A. In the evaluation of the articles, we looked to see whether confounders were take into consideration in the assessments. Q. Nowhere in your report do you discuss the potential confounding factor of BMI, correct? A. Not not that I'm aware of. But, remember, a confounder has to have preceded the use of a particular exposure. Q. Nowhere in your report do you discuss the potential confounder of hormone replacement therapy, correct? |

| | Page 114 | | Page 116 |
|--|---|----------------------|---|
| 1 | Q. My question is different, though. | 1 | So I do state that in the |
| 2 | Nowhere in your report do you | 2 | conclusions. |
| 3 | discuss hormone replacement therapy as a potential | 3 | Q. Please look back over to Exhibit |
| 1 | confounder for the talcum powder and ovarian | 4 | Number 9, Dr. Rothman's 2000 document. |
| | cancer studies, correct? | 5 | A. Yes. |
| 6 | A. That's correct, because it's | 6 | Q. Report. |
| 7 | unlikely to be a confounder. | 7 | A. Yes. |
| 8 | Q. Nowhere in your report do you | 8 | Q. Over on page 6. |
| 9 | discuss smoking as a potential confounder, | 9 | A. Yes. |
| 10 | correct? | 10 | Q. He does an analysis of dose response |
| 11 | A. I don't believe that smoking is a | 11 | and actually has two figures there where he's |
| | strong risk factor for ovarian cancer. | 1 | analyzing the trend from the data, correct? |
| 13 | Q. My question is different, Doctor. | 13 | A. It appears that is what he is doing, |
| 14 | My question is: Do you anywhere in | 1 | yes. I don't know what data he is using to derive |
| | your report discuss smoking | | that. |
| 16 | A. No. | 16 | Q. You did not do an analysis like |
| 17 | Q as a potential confounder? | | it |
| 18 | A. No. | 18 | A. No, I did not. |
| 19 | Q. Do you discuss anywhere in your | 19 | Q in your report |
| | report any of the potential confounders that are | 20 | A. I did not. |
| | listed in the studies that you reviewed looking at | 21 | Q like what is shown on page 6? |
| | talcum powder use and ovarian cancer? | 22 | A. No. |
| 23 | A. I don't believe I discussed it in | 23 | MR. TISI: One at a time. One |
| | the report because the studies that were done and | 24 | at a time. Sorry. |
| | Page 115 | | Page 117 |
| 1 | also combined together in meta-analyses had done | 1 | THE WITNESS: No, and |
| | their best job at trying to control for known risk | 2 | Dr. Rothman did not recommend that we do |
| | factors for ovarian cancer. | 3 | that. |
| 4 | Q. Nowhere in your report do you | 4 | BY MR. HEGARTY: |
| 5 | analyze dose-response trends, correct? | 5 | Q. Did you actually have a discussion |
| 6 | A. I believe that's not true. | | with him about it? |
| 7 | I believe at the end of my report | 7 | A. I don't recall. |
| 8 | (Reviews document). | 8 | Q. With regard to dose response, you |
| 9 | Q. Let me ask a different way. Let me | 9 | only cite a single study that found a |
| 10 | withdraw that question. | 10 | dose-response trend. |
| 11 | A. Okay. | 11 | That's Cramer on page 8, correct? |
| 12 | Q. Nowhere in your report do you do an | 12 | MR. TISI: Objection. |
| 13 | analysis of the various dose-response findings | 13 | Misstates. |
| 1 | from the studies and report on what the trends are | 14 | THE WITNESS: In my report? |
| | as to those studies, correct? | 15 | BY MR. HEGARTY: |
| 16 | A. I believe I could state in | 16 | Q. In your report, Doctor. |
| 1 - 0 | "Considering the presentation of the state of | 17 | MR. TISI: Misstates the |
| | "Considering the preponderance of the evidence, | | |
| 17 | including after controlling for known risk and | 18 | evidence and his report. |
| 17 18 | | 18 19 | evidence and his report. THE WITNESS: Where? Where |
| 17 18 19 | including after controlling for known risk and | | • |
| 17 18 19 20 | including after controlling for known risk and protective factors for ovarian cancer, evidence of | 19 20 | THE WITNESS: Where? Where |
| 17 18 19 20 21 | including after controlling for known risk and protective factors for ovarian cancer, evidence of a trend of increasing risk of ovarian cancer with | 19 20 | THE WITNESS: Where? Where is that located? |
| 17 18 19 20 21 22 | including after controlling for known risk and protective factors for ovarian cancer, evidence of a trend of increasing risk of ovarian cancer with increasing talc applications" and that was | 19 20 21 22 | THE WITNESS: Where? Where is that located? BY MR. HEGARTY: |
| 17 18 19 20 21 22 23 | including after controlling for known risk and protective factors for ovarian cancer, evidence of a trend of increasing risk of ovarian cancer with increasing talc applications" and that was evident from the 1999 publication and the 2012 | 19 20 21 22 | THE WITNESS: Where? Where is that located? BY MR. HEGARTY: Q. In the middle paragraph of page 8 |

| 1 | Page 118 | 1 | Page 120 Other than foir point Lat's add |
|--|---|--|--|
| $\begin{vmatrix} 1 \\ 2 \end{vmatrix}$ | yes. O You don't gite only other study in | $\begin{vmatrix} 1 \\ 2 \end{vmatrix}$ | Q. Other than fair point. Let's add Schildkraut. |
| | Q. You don't cite any other study in | $\frac{2}{3}$ | |
| 3 | your report that discusses a dose-response trend, | | Other than Cramer and Schildkraut, |
| | correct? | 4 | |
| 5 | MR. TISI: Objection. | 5 | increasing frequency, duration, or cumulative |
| 6 | Misstates his report. | 6 | exposure from any other study, correct? |
| 7 | THE WITNESS: Again, I | 7 | MR. TISI: Objection. |
| 8 | selected Cramer's study as a as the | 8 | Misstates his report. |
| 9 | most recent relevant article that shows a | 9 | THE WITNESS: Okay. So, as |
| 10 | dose response. | 10 | you know, the Cramer study was the New |
| | BY MR. HEGARTY: | 11 | England case-control study that was |
| 12 | Q. Going back to my question. | 12 | continued to build cases and controls, |
| 13 | You don't discuss anywhere else in | 13 | and so the 1992 report that we published |
| | your report any other study that reported on a | 14 | |
| | dose-response that reported a dose-response | 15 | fewer cases and controls showing a dose |
| 16 | trend, correct? | 16 | response. |
| 17 | A. It's not specifically stated here in | 17 | As you add more cases and |
| 18 | the report. | 18 | controls to that particular that |
| 19 | MR. TISI: And, again, | 19 | particular case and control series, you |
| 20 | objection. There are other discussions | 20 | continue to see a dose response. And as |
| 21 | in the report. | 21 | you even continue to add more in the |
| 22 | MR. HEGARTY: Chris, come on. | 22 | 2016, it continues to show that kind of |
| 23 | Let's limit your objections to | 23 | trend. |
| 24 | MR. TISI: Okay. I'm happy to | 24 | So, no, I did not I did not |
| | | | |
| | Page 119 | | Page 121 |
| 1 | Page 119 do that. | 1 | Page 121 specifically talk about the 1992 and the |
| 1 2 | | 1 2 | _ |
| | do that. | | specifically talk about the 1992 and the |
| 2 | do that. MR. HEGARTY: form, and you | 2 | specifically talk about the 1992 and the 1999 papers because the 2016 paper was the most recent one. |
| 2 3 | do that. MR. HEGARTY: form, and you know that that was an improper objection, | 2 3 | specifically talk about the 1992 and the 1999 papers because the 2016 paper was the most recent one. |
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| 2 3 4 5 6 | do that. MR. HEGARTY: form, and you know that that was an improper objection, and you were coaching the witness. MR. TISI: You know you know that you're misstating his report. MR. HEGARTY: Then it's up for | 2 3 4 5 6 7 | specifically talk about the 1992 and the 1999 papers because the 2016 paper was the most recent one. BY MR. HEGARTY: Q. You are not an author on Cramer's 2016 paper? |
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| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 | do that. MR. HEGARTY: form, and you know that that was an improper objection, and you were coaching the witness. MR. TISI: You know you know that you're misstating his report. MR. HEGARTY: Then it's up for the doctor to tell me I'm misstating his report. MR. TISI: No, it's up to you to ask fair questions. MR. HEGARTY: You know how that works. MR. TISI: It's up to you to ask fair questions. MR. HEGARTY: It is a fair question. BY MR. HEGARTY: Q. Doctor, you do actually A. Actually actually, if I may, I believe also I cite Schildkraut's study | 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 | specifically talk about the 1992 and the 1999 papers because the 2016 paper was the most recent one. BY MR. HEGARTY: Q. You are not an author on Cramer's 2016 paper? A. I am not, but it is from that data set. Q. You're not an author on the Schildkraut paper? A. I am not. Q. Going back to my question. The only two studies you report on as showing an increasing trend with increasing dose in your report are the Cramer and Schildkraut study, correct? MR. TISI: Objection. Misstates his report. THE WITNESS: Yeah, those those are what was stated in the report as what I thought ample evidence to |

| D 122 | D 124 |
|---|---|
| Page 122 1 that reported no dose response, the Davis study on | Page 124 1 MR. HEGARTY: You can show it |
| 2 page 14 and the Taher study on pages 13 and 14, | 2 him when you do your questioning, Chris. |
| 3 correct? | 3 You know how that works. |
| 4 A. The Davis study on page 13. | 4 MR. TISI: No. You know how |
| 5 Q. 14. | 5 it works. You can't ask him about a |
| 6 A. Oh, 14. I'm sorry. | 6 study and not show him the study. |
| 7 Yes. | 7 MR. HEGARTY: I can withdraw |
| 8 Q. And then the Taher study you also | 8 the question. That's absolutely |
| 9 report did not find an increasing trend or dose | 9 permitted. |
| 10 response, correct? | 10 MR. TISI: Well |
| 11 A. However, in the Davis article, they | 11 BY MR. HEGARTY: |
| 12 did not lump together frequency and duration of | 12 Q. Look over on page 355 of your |
| 13 use to get a cumulative exposure measure. So it | 13 article. |
| 14 was they did not. For whatever reason, they chose | 14 A. Uh-huh. Hold on a second. Let |
| 15 not to do that. | 15 me let me just get the article. |
| And with the Taher study, it was | 16 Q. It's one of the exhibits. |
| 17 again, it was not what I would consider to be an | 17 A. Yeah. |
| 18 appropriate a complete ascertainment of | MR. TISI: He's going to |
| 19 exposure. | 19 his his ones. |
| 20 Q. You mentioned your '92 and '99 | THE WITNESS: Okay. |
| 21 study. | 21 BY MR. HEGARTY: |
| 22 Your actually your '99 study, as | Q. 355. Lower left-hand corner at the |
| 23 we looked at a short time ago, found no dose | 23 bottom. Tell me when you're there. |
| 24 response, correct? | 24 A. Yep. There. |
| Page 123 | Page 125 |
| 1 MR. TISI: Objection. | 1 Q. No. This part. This page. |
| 2 THE WITNESS: No, that's not | 2 (Indicates). |
| 3 true. The 1999 article with Cramer? | 3 A. 355? |
| 4 BY MR. HEGARTY: | 4 Q. 355. |
| 5 Q. Well, let me go back over what you | 5 A. Oh, I'm sorry. Yep. I'm here. |
| 6 said. | 6 Q. You wrote: |
| 7 A. Well, let me go look at the data. | 7 "Most talc and ovarian cancer |
| 8 Let me pull up the article. | 8 studies" |
| 9 Q. I got to ask my question. | 9 A. I'm sorry. On which? On which? |
| MR. TISI: Well, no. You said | 10 Q. Lower left-hand corner. |
| his article does not show a dose | 11 A. Okay. Got it. Yep. |
| response. He says he wants to look at his table. | 12 Q. "Most tale and ovarian cancer |
| | 13 studies that have addressed dose response, |
| MR. HEGARTY: Withdraw my withdraw my question. Let me ask another | 14 including this one, have failed to demonstrate |
| 7 1 | 15 consistent dose response relationships with |
| 16 question. 17 MR. TISI: You can't do that. | 16 measures of the intensity of the exposure, |
| No, you can't do that. | 17 especially when the trend is examined among users 18 only." |
| 19 MR. HEGARTY: Yes, I can. | 19 And you agreed with me that was a |
| i - | 20 true statement back then, correct? |
| TAN TO THE TOTAL STATE OF THE TANK THE | |
| MR. TISI: You can't do that. MR HEGARTY: Let me ask a | [2] A Yeah and that is a true statement |
| 21 MR. HEGARTY: Let me ask a | 21 A. Yeah, and that is a true statement. 22 If you look at the table by which this comes and |
| MR. HEGARTY: Let me ask a different question. | 22 If you look at the table by which this comes and |
| 21 MR. HEGARTY: Let me ask a | |

| | _ | | |
|-----|--|----|--|
| | Page 126 | | Page 128 |
| 1 | see that dose response. | 1 | Q. Dr. Rothman writes in the first |
| 2 | But when you start to take into | 2 | sentence: |
| 3 | account the time periods when women were exposed, | 3 | "Cohort studies do not suffer from |
| | excluding times when subsequent to a tubal | 4 | recall bias, but recall bias is an issue for |
| | ligation or a hysterectomy, and then in addition, | 5 | case-control studies that obtain exposure |
| 1 | excluding times when there was not ovulation, you | | information from subject interviews." |
| | see a significant dose response going forward. | 7 | Do you agree with that statement? |
| 1 | Well, you see a dose response. I don't like the | 8 | A. No, and neither does he because we |
| | word "significant," but you can see that it goes | 9 | specifically talked about the fact that cohort |
| 1 | from 1.0 to 1.8. | | studies can indeed have recall bias in our report. |
| 11 | So there is a dose response when you | 11 | Q. Did he agree with that statement |
| 12 | take into account a refinement of the an | 12 | when he wrote it back in 2000? |
| | appropriate refinement of the exposure. | 13 | A. I have no idea what what I |
| 14 | | 14 | think I have no idea what he I only know |
| 15 | Number 9, Dr. Rothman's November 28, 2000 report. | | what he agreed to with respect to our report. |
| 16 | - | 16 | And I think in his 2000 report, he |
| 17 | Q. Please turn over to page 4. | 17 | was making a general conclusion about cohort |
| 18 | | | studies being designed specifically to look at the |
| 19 | | | exposure and unexposed, and actually recruiting |
| 20 | | | participants as as being unexposed or not |
| | Dr. Rothman writes | | exposed and then following them forward in time. |
| 22 | MR. TISI: Give him a chance | 22 | So, ideally, you're right. He's |
| 23 | | | right. They would not suffer from recall bias if |
| 24 | 8 | | you are able to identify them prior to the outcome |
| - | Page 127 | | Page 129 |
| 1 | | 1 | of interest and to be able to capture all of the |
| 2 | | | exposure that occurred over a period of time. |
| 3 | - | 3 | Q. Please look at the third line of |
| 4 | | | that same paragraph. Dr. Rothman writes: |
| 5 | - 1 | 5 | "Recall bias can readily introduce |
| 6 | | _ | enough bias to produce the modestly-sized overall |
| 7 | | | effect (relative risk equals 1.3) that emerges |
| 8 | • | | from these studies." |
| 9 | - | 9 | Do you agree with that statement? |
| | BY MR. HEGARTY: | 10 | A. I think it's not a yes or no. I |
| 11 | Q. Dr. Rothman writes: | | think in some situations if there is the if the |
| 12 | ~ | | recall bias is applicable to the exposure being |
| | measure of talc dose within the upper reproductive | | assessed, and I believe there are many studies |
| 1 | tract." | | that and many comments even during the conference |
| 15 | | | in 2000 I mean, in 1994 where Dr. Hartge |
| 16 | , | | specifically said those who were exposed to an |
| 17 | | | event in their lifetime that was daily over |
| 1 / | v. (maicaco). | 1/ | cront in their metric that was daily over |

18 decades are unlikely to have an issue related to

Please turn over to page 5 of that

The section on "Confounding."

19 recall bias.

21 document.

Q.

A.

Q.

A.

Yes.

20

22

23

24

Q.

Q.

23 "Recall Bias."

A.

18

19

20

22

24

Oh, yeah. Got it. Okay.

21 it's feasible or can possibly be done.

Yes.

Do you agree with that statement?

Please look at the next section on

Well, it's ideally. I don't think

| | Page 120 | | Page 132 |
|-------|--|----|---|
| 1 | Page 130 Q. Tell me when you're there. | 1 | meta-analyses meta-regression analysis, is not |
| 2 | · | l | consistent with a causal interpretation for tale |
| 3 | | | exposure. Instead it suggests that some as yet |
| | section. Dr. Rothman writes: | | unidentified bias accounts for overall modest |
| 5 | | | the overall modest relation between talc exposure |
| | yet unidentified risk factors for ovarian cancer | | and ovarian cancer risk." |
| 1 | could be important confounders, and several such | 7 | First of all, did I read that |
| | factors in the aggregate could give rise to an | 8 | correctly? |
| 1 | overall association as weak as the one between | 9 | A. You did. |
| 10 | talc and ovarian cancer." | 10 | Q. Do you agree with those statements |
| 11 | Do you agree with that statement? | 11 | |
| 12 | | 12 | part of this report? |
| 13 | likely in this situation because any unmeasured | 13 | MR. TISI: Again again, you |
| 1 | confounder would have to have preceded the use of | 14 | know, in fairness to the witness, you |
| 1 | talc, and women have been the women who are | 15 | have picked out sentences and skipped |
| 16 | greatest risk, in my view, with respect to talc | 16 | sentences. If you're going to ask him |
| 17 | have been using it for decades, even as early as | 17 | about about things, let him read |
| 18 | their during during childhood. | 18 | let him read the paragraph and he can |
| 19 | So to think of an unmeasured | 19 | answer your question. |
| 20 | confounder that would have preceded that are I | 20 | BY MR. HEGARTY: |
| 21 | don't know what it could possibly be. | 21 | Q. You can answer. |
| 22 | And when people talk about obesity | 22 | MR. TISI: No. He can answer |
| 23 | or hormone replacement therapy, or any of the | 23 | when he's had when he feels |
| 24 | other things, they would serve and if you were | 24 | comfortable reading it. |
| | Page 131 | | Page 133 |
| 1 | to adjust for them, they would serve as mediators | 1 | Do not feel compelled to |
| 2 | and would attenuate the relative risk. | 2 | answer questions about picked-apart |
| 3 | | 3 | sentences. |
| 4 | | 4 | THE WITNESS: Yeah. I'm ready |
| 5 | | 5 | to answer. |
| 6 | , , , , , , , , | 6 | I do not know what estimates |
| 7 | stopping point, we've been going for a | 7 | he used for calculating these these |
| 8 | | 8 | curves. |
| 9 | | 9 | The other thing that I don't |
| 10 | | 10 | know is how dose was assessed in his |
| 11 | | 11 | making of these curves. |
| 12 | 3 | 12 | So I can't really comment on |
| 1 | relations in epidemiology and in the pathogenesis | 13 | that. |
| | cancer in particular is a monotonically increasing | l | BY MR. HEGARTY: |
| 1 | relation between measures of exposure and disease | 15 | Q. Please turn next over to the section |
| | risk." | 16 | |
| 17 | , 8 | 17 | MR. TISI: Wait. Since we're |
| 18 | • | 18 | going to a new one, let's take a break. |
| 1 | that's what we are looking for. | 19 | MR. HEGARTY: Okay. Off the |
| 20 | | 20 | record. |
| 1 | page 6. | 21 | (Recess: 11:31 a.m |
| 22 23 | 7 17 | 22 | 11:32 a.m.) |
| 」ノ≺ | "Thus, the observed pattern, whether | l | BY MR. HEGARTY: |
| | based on individual studies or from the combined | 24 | Q. I'll finish with this document. |

| Page 134 | Page 136 |
|---|--|
| 1 Please turn to the "Biologic Mechanism" section. | 1 is unknown, plausible mechanisms may involve |
| 2 A. Yes. | 2 inflammation." |
| 3 Q. Please look towards the bottom of | 3 Did I read that correctly? |
| 4 that paragraph. | 4 A. You did. |
| 5 First of all, are you familiar with | 5 Q. You are not citing in your report |
| 6 this section? | 6 that there is let me start over again. |
| 7 A. Yes, I am. | 7 You're not claiming in your report |
| 8 Q. Dr. Rothman writes towards the | 8 that there is a clear biologic mechanism by which |
| 9 bottom of that section: | 9 talc causes ovarian cancer, correct? |
| 10 "Without a clear biologic mechanism | 10 MS. PARFITT: Objection. |
| 11 for talc to cause ovarian cancer, an inference | 11 MR. TISI: Objection. |
| 12 that talc does cause ovarian cancer would be an | 12 Misstates the standard. |
| | 13 THE WITNESS: No, I don't |
| 13 example of a 'black-box' inference, meaning that | |
| 14 the inference lacks a biologic foundation." | believe I'm making I don't believe that is inferred from this statement. |
| Do you agree with that statement? A. No, I don't, and, in fact, | 16 BY MR. HEGARTY: |
| | |
| 17 Dr. Rothman cited our 1999 article. And if you go | 17 Q. To make it clear because I'm not |
| 18 to read our 1999 article, there was a discussion | 18 sure I understand your answer. |
| 19 of the biological plausibility and the fact that | 19 You're not saying in your report |
| 20 there was much evidence to suggest that. | 20 anywhere that there is a clear biologic mechanism |
| So I do not know why he made that | 21 by which talc causes ovarian cancer, correct? |
| 22 conclusion. | 22 A. That |
| Q. You don't say anywhere in your | MR. TISI: Objection. |
| 24 report that there is a clear biologic mechanism | 24 MS. PARFITT: Objection. |
| Page 135 | Page 137 |
| 1 for talc to cause ovarian cancer, correct? | 1 THE WITNESS: I am stating |
| 2 MR. TISI: Objection. | 2 that there are many possible mechanisms |
| 3 THE WITNESS: Well, I don't | 3 that could be in play, but we do not know |
| 4 believe that's true. | 4 what that exact biological mechanism is. |
| 5 I believe we actually at the | 5 BY MR. HEGARTY: |
| 6 under report and I'll tell you where | 6 Q. Is it your opinion that there is a |
| 7 it is. Under there is lack of on | 7 clear biologic mechanism by which talc causes |
| 8 page 19, there's a section on this. | 8 ovarian cancer? |
| 9 There's a lack of evidence | 9 MR. TISI: Objection. |
| regarding the biologic plausibility of | THE WITNESS: I believe there |
| 11 talc. That's the interpretation that | 11 is. |
| others have made, and we specifically | 12 BY MR. HEGARTY: |
| talk about a number of of ways in | Q. What is that clear biologic |
| which there is a biological plausibility. | 14 mechanism and where is that referenced in your |
| 15 It's a short section, but it | 15 report? |
| certainly does not agree with what | 16 A. I well, you're asking me if I |
| Dr. Rothman has indicated in his earlier | 17 believe there is a clear biological mechanism, and |
| 18 report. | 18 the biological mechanism is summarized by evidence |
| 19 BY MR. HEGARTY: | 19 to show transvaginal migration of top particulates |
| 20 Q. Staying with that section in your | 20 by the potential for talc particulates to embed in |
| 21 report, at the very end of page 19 before the | 21 inclusion cysts that has been shown to be able to |
| 22 "Summary," you state: | 22 induce inflammation. |
| | |
| 23 "Although the exact pathogenic 24 mechanism by which talc may incur carcinogenesis | 23 Those are all plausible biological 24 processes that could explain the carcinogenic or |

| 1 | Page 138 | | Page 140 |
|---|--|--|--|
| 1 | underlie the carcinogenic process. | 1 | "Causation is the most reasonable |
| 2 | Q. Are you equating plausibility of | 2 | explanation for the association between perineal |
| 3 | these mechanisms with clear biologic mechanisms? | | exposure to talc and ovarian cancer." |
| 4 | MS. PARFITT: Objection. | 4 | As to that opinion, does it apply to |
| 5 | THE WITNESS: No. My my | 5 | all subtypes of ovarian cancer? |
| 6 | job as an epidemiologist is to be able to | 6 | A. We evaluated it based on the |
| 7 | show biological plausibility, and I | 7 | totality of epithelial ovarian cancer. |
| 8 | believe that has been effectively shown. | 8 | Q. Well, does it does that statement |
| | BY MR. HEGARTY: | | apply to mucinous ovarian cancer in talcum powder |
| 10 | Q. Well, have you shown in your report | | exposure? |
| | a clear biologic mechanism for talc to cause | 11 | A. It was not an analysis specific to |
| | ovarian cancer? | | histologic subtypes. It was based on all |
| 13 | MR. TISI: Objection. This is | | epithelial ovarian tumors. |
| 14 | now about the fifth time you've asked the | 14 | Q. Understood. |
| 15 | question. | 15 | But sitting here today, is it your |
| 16 | THE WITNESS: Yeah. | _ | opinion that talcum powder use in the genital area |
| 17 | MR. TISI: He's talked about | 17 | |
| 18 | plausibility. | 18 | A. I can't respond to that because |
| 19 | Go ahead. | _ | there are the studies that are in the |
| 20 | | | literature were not designed to specifically |
| 21 | don't believe we for even cigarette | | target, for example, a case-control study of |
| 22 | smoking and lung cancer that we can't | | mucinous ovarian cancer. |
| 23 | specifically say what that clear | 23 | They did a case-control study of |
| 24 | pathological mechanism might be, or what | | epithelial ovarian cancer, and then based on |
| | Page 139 | | Page 141 |
| 1 | the chemical component in the cigarettes | 1 | however many cases they had of the various |
| 2 | are that are specifically inducing the | | subtypes, they looked at those, but those studies |
| 3 | cancer. | - | subtypes, they looked at those, but those studies |
| | | 3 | were not designed specifically to look at the |
| 4 | | | were not designed specifically to look at the |
| 4 5 | We know, but I believe it's | 4 | specific risk factors for that particular |
| 5 | We know, but I believe it's indisputable that people believe that | 4 5 | specific risk factors for that particular histologic subtype. |
| 5 6 | We know, but I believe it's indisputable that people believe that cigarettes cause cause lung cancer. | 4 5 6 | specific risk factors for that particular histologic subtype. And I think the approach that's been |
| 5 6 7 | We know, but I believe it's indisputable that people believe that cigarettes cause cause lung cancer. BY MR. HEGARTY: | 4 5 6 7 | specific risk factors for that particular histologic subtype. And I think the approach that's been used throughout the literature is to keep |
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| 5 6 7 8 9 | We know, but I believe it's indisputable that people believe that cigarettes cause cause lung cancer. BY MR. HEGARTY: Q. Can you then translate that to talc and ovarian cancer? | 4 5 6 7 8 9 | specific risk factors for that particular histologic subtype. And I think the approach that's been used throughout the literature is to keep epithelial ovarian tumors lumped together. Q. Understanding that, but is it your |
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| | Page 142 | | Page 144 |
|---------------------------------------|--|----|--|
| 1 | Page 142 serous, and all the other histologic subtypes are | 1 | and serous ovarian cancer? |
| | much smaller in terms of numbers that are found in | 2 | A. No, because the studies, as I |
| | the studies and, therefore, I cannot make that | | indicated before, were not designed to be able to |
| l . | kind of conclusion. | | look at those subtypes. And the reason we could |
| 5 | Q. Is it your opinion that genital talc | | look at it with serous is because they make up the |
| | use in the start over again. | | majority of the cases. |
| 7 | Is it your opinion that talc use in | 7 | Q. Without doing that analysis, how can |
| 8 | the genital area causes serous adenocarcinoma? | 8 | you say in your report that the association is |
| 9 | A. Given that serous cancer makes up | | stronger and more consistent for the subtype of |
| 10 | about 90 percent of the incidents, I would say | | serous ovarian cancer? |
| 11 | yes. | 11 | In other words, wouldn't you have to |
| 12 | Q. In your report in the Executive | 12 | do an analysis between serous and the other |
| 13 | Summary, second paragraph about four lines down, | 13 | subtypes to make that statement? |
| 14 | when you're referring to talc and ovarian cancer | 14 | A. Well, others have looked at |
| 15 | you say: | 15 | specifically the serous tumors and found the |
| 16 | "An association that is stronger and | 16 | association to be more strongly when it's |
| 17 | more consistent for the subtype" | 17 | restricted to that particular ones, and it doesn't |
| 18 | A. I'm sorry. I didn't mean to | | necessarily suggest that the others that there |
| 19 | interrupt. Show me where exactly in the Executive | 19 | isn't an association with the others. |
| 20 | Summary. | 20 | I believe it suggests that that |
| 21 | MR. TISI: Do you mind me | | particular histologic subtype seems to show an |
| 22 | showing him? | | association consistently. |
| 23 | THE WITNESS: "An association | 23 | Q. But to be clear, you did not do a |
| 24 | that is stronger." | 24 | separate analysis of comparing the risk ratios or |
| | Page 143 | | Page 145 |
| 1 | I have it. Thanks. Go ahead. | | odds ratios between clear cell, endometrioid, and |
| | BY MR. HEGARTY: | | mucinous to serous? |
| 3 | Q. Let me go back to my question. | 3 | A. Not in my evaluation. Not in this |
| 4 | In your report, you state in the | | particular report. Though, in my earlier |
| 5 | 1 & 1 | | publications, I have stratified it out. |
| | use and ovarian cancer: | 6 | Q. Does your overall opinion as it |
| 7 | "An association that is stronger and | | relates to epithelial ovarian cancer and talc use |
| | more consistent for the subtype of serous ovariar | | apply to borderline tumors? |
| | cancer." | 9 | A. I think my as I recall, my study |
| 10 | First of all, did I read that | | in 1999 may have been the few studies to look at |
| 12 | correctly? | 12 | borderline ovarian tumors and given that yeah. So I don't believe that there is |
| | A. Well, you only read part of the sentence. | | besides my article, there haven't been a lot of |
| 13 | "The principal finding from the | | any other studies I'm aware of that are |
| | literature is a consistent association between | | specifically focusing on borderline ovarian |
| | frequent talc use and ovarian cancer." | | tumors. |
| 17 | That's the first part, and then it | 17 | Q. Understood, but going back to my |
| | says: | | question. |
| 19 | "An association that is stronger and | 19 | Does your opinion as it relates to |
| | more consistent for the subtype of serous ovariar | | _ |
| | cancer." | | borderline tumors? |
| $\begin{vmatrix} 21\\22\end{vmatrix}$ | Q. Did you do an analysis as it relates | 22 | A. Yes, I believe it does. |
| l . | to the strength and consistency of the other | 23 | Q. And did you do any particular |
| | subtypes, clear cell, endometrioid, and mucinous | | |
| 24 | subtypes, clear cell, chaometroid, and macmoun | | |

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| 1 | | | |
|---|---|--|--|
| | Page 150 | | Page 152 |
| | genital area of women," is it your opinion that | 1 | wish. |
| | there is causation for a woman who has had a | 2 | THE WITNESS: I do not have |
| 3 | single application of talc to the genital area? | 3 | an opinion that there is a particular |
| 4 | A. I think the causation that I've | 4 | amount of exposure that is necessary to |
| | indicated is predicated on exposure for a long | 5 | put a woman at greater risk of ovarian |
| 6 | period of time over decades. | 6 | cancer, but that the risk increases with |
| 7 | Q. Hopefully, that was where I was | 7 | greater amount of exposure. |
| 8 | going to start with that question. | 8 | BY MR. HEGARTY: |
| 9 | What is the necessary exposure level | 9 | Q. You mentioned earlier that the use |
| 10 | 1 2 | | |
| 11 | your causation opinion? | 11 | Do you remember telling me that? |
| 12 | MR. TISI: Objection. | 12 | MR. TISI: Objection. |
| 13 | Objection | 13 | THE WITNESS: In my my |
| 14 | THE WITNESS: I don't | 14 | view, that that decades of use would |
| 15 | MR. TISI: to form. | 15 | are certainly those that are at the |
| 16 | THE WITNESS: I don't believe | 16 | highest risk, in my opinion. |
| 17 | there is a known dose that needs to be | | BY MR. HEGARTY: |
| 18 | present for there to be a risk, and I | 18 | Q. When you say "decades of use," how |
| 19 | would expect that other factors that are | | many decades? |
| 20 | present that might promote ovarian cancer | 20 | A. I don't have a particular number, |
| 21 | might work with the exposure of talc. We | | but I don't have a particular number, but |
| 22 | just we just don't know. | | decades implies regular use for a long period of |
| 23 | BY MR. HEGARTY: | | time directly applied to the perineal area. |
| 24 | Q. Do you have an opinion, sitting here | 24 | Q. In fact, in your report, you do talk |
| | Page 151 | | Page 153 |
| 1 | today, as to the necessary frequency and duration | 1 | about in relation to your opinions that the use |
| | | 1 | about in relation to your opinions that the use |
| 2 | of talcum powder use for it to be causal with | | must be frequent, correct, to be causal? |
| | of talcum powder use for it to be causal with regard to ovarian cancer? | | |
| | _ | 2 | must be frequent, correct, to be causal? |
| 3 | regard to ovarian cancer? | 2 3 4 | must be frequent, correct, to be causal? A. And where do I state that, please? |
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| 3 4 5 6 7 | regard to ovarian cancer? MR. TISI: Objection to form. THE WITNESS: No, I don't. It's quite possible that somebody who smokes one or two cigarettes a day can be | 2 3 4 5 6 7 8 | must be frequent, correct, to be causal? A. And where do I state that, please? Q. Well, you state that well, I can ask in a different way. Look over to page 20. A. Yes. |
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Page 154 Page 156 1 THE WITNESS: Do I believe 1 The frequency is more of a linear 2 2 kind of an assessment, in my view. There isn't a the cause of most ovarian cancers is 3 3 cut point by which you can then define somebody as unknown. 4 4 saying, It's okay to use it for this number of I would say it is more likely 5 5 years, but not that number of years. That that the cause of ovarian cancer -- that 6 information is just not known. 6 there are causes of ovarian cancers that 7 My question is a little bit 7 are unknown than that are known. 8 BY MR. HEGARTY: 8 different than that. 9 When you wrote the phrase "A long With regard to risks for ovarian 10 period of time," what were you meaning by that 10 cancer generally, do gene mutation such as BRCA1 11 phrase? 11 or BRCA2 cause ovarian cancer? 12 12 A. The counterfactual to that the would A. Yes. 13 be a short period of time. So not a short period 13 Q. Do the Lynch syndrome genes cause 14 of time but a long period of time. 14 ovarian cancer? 15 So when you wrote the phrase "A long 15 A. I believe so. 16 period of time," you did not have a particular 16 Q. Does endometriosis cause 17 frequency or duration in mind; is that fair? 17 endometrioid ovarian cancer? 18 That -- I think that's fair, and in 18 A. I'm not sure of that literature. 19 the publications that I've authored, we actually 19 Does endometriosis cause clear cell O. 20 use applications as the exposure as opposed to 20 20 adenocarcinoma? 21 I'm not -- I'm not familiar with 21 years. Because somebody could have used talc for A. 22 20 years but only applied it once a week or only 22 that literature. 23 on diaphragms and, therefore, using that kind of 23 Does HRT use -- hormone replacement O. 24 frequent -- frequency in terms of years is not --24 therapy use cause ovarian cancer? Page 155 Page 157 1 is not accurate. A. Again, I didn't review the extent of 1 2 And going back to the Executive 2 that literature for the purpose of this meeting. 3 3 Summary section on page 6. Q. Does obesity cause ovarian cancer? 4 4 I have not reviewed that literature A. Yes. A. 5 5 either. Q. Going back to that phrase we were 6 talking about with regard to serous ovarian 6 O. Does polycystic ovarian syndrome 7 cancer. 7 cause ovarian cancer? 8 Uh-huh. 8 I have not reviewed those -- those A. A. 9 Q. You use a phrase "is a consistent 9 items either. 10 association between frequent talc use and ovarian 10 Q. My questions all included the word 11 cancer." 11 "cause." 12 What were you meaning when you said 12 Do you know whether any of those 13 "frequent" in that sentence? 13 subject areas, any of those exposures are risk 14 A. 14 factors for ovarian cancer? Can you say that? Applications. Did you have a particular number in 15 15 O. Yes, I think that there is evidence. 16 mind either by week or by month or by total? 16 Certainly there have been studies that have shown 17 17 that obesity seems to be associated with ovarian Well, the only number that I can 18 look at is that which was cited in our papers, and 18 cancer in some studies. 19 I believe that was more than 10,000 applications 19 I don't remember all the other ones 20 is where we saw the greatest risk. I believe that 20 that you mentioned. 21 to be the case. 21 Let me go back over them then. Do you agree that the cause of most 22 Is endometriosis a risk factor for 22 23 ovarian cancers is unknown? 23 endometrioid ovarian adenocarcinoma? 24 MR. TISI: Objection. 24 Yeah. I'm not familiar with that Α

| | Daga 159 | | Page 160 |
|--|---|----------------------------------|--|
| 1 | Page 158 literature. | 1 | factors that are present in a particular |
| $\frac{1}{2}$ | Q. Is hormone replacement therapy use a | 2 | person and making a qualitative opinion |
| | risk factor for ovarian cancer? | 3 | as to whether it is more likely than not |
| 4 | A. I believe hormone replacement | 4 | that the ovarian cancer could have been |
| l _ | | 5 | attributed to one factor versus another. |
| 5 | | l | BY MR. HEGARTY: |
| | of the estrogen-related cancers. | 7 | |
| 7 | Q. Is polycystic ovarian syndrome a risk factor for ovarian cancer? | | Q. Do you know of any publication where |
| | | 8 9 | 2, |
| 9 | A. I'm not familiar with that | 10 | MR. TISI: Objection. He's |
| - | literature. | 11 | not case-specific person. THE WITNESS: I don't believe |
| 11 | Q. Is incessant ovulation a risk factor | 12 | I'm aware of that. |
| | for ovarian cancer? | l | |
| 13 | A. It's a hypothesis that Dr. Cramer | l | BY MR. HEGARTY: |
| | has put forward as a potential mechanism by which | 14 | Q. Do you agree that case-control |
| 1 | ovarian cancer might occur. | 15 | studies are more subject to recall bias than |
| 16 | Q. Is douching a risk factor for | | cohort studies? |
| 1 | ovarian cancer, in your opinion? | 17 | MR. TISI: Objection. |
| 18 | A. I'm not familiar with the extent of | 18 | THE WITNESS: I think |
| | that literature. | 19 | correctly done case-control studies and |
| 20 | Q. Is smoking a risk factor for ovarian | 20 | correctly done cohort studies are let |
| | cancer, in your opinion? | 21 | me rephrase that answer. |
| 22 | A. Again, I'm not I'm not up to date | 22 | I think it depends on the |
| | on that literature. | 23 | particular exposure that's being |
| 24 | Q. Is Ashkenazi Jewish heritage a risk | 24 | measured. I think that both case-control |
| | Page 159 | | Page 161 |
| 1 | factor for ovarian cancer? | 1 | studies and cohort studies can be subject |
| 2 | | 2 | can be subject to a certain amount of |
| 3 | Q. Does a family history of ovarian | 3 | recall bias. |
| 4 | | 4 | So it really depends on what |
| 5 | A. Yes, it does. | 5 | the exposure is that you're looking at |
| 6 | Q. Does a family history of breast | 6 | and how the study was designed. |
| 7 | cancer increase the risk of ovarian cancer? | 7 | BY MR. HEGARTY: |
| 8 | A. Yes, it does. | 8 | Q. With regard to your discussion about |
| 9 | Q. Does a woman's risk of ovarian | 9 | recall bias, did you discuss the Schildkraut |
| 10 | cancer go up with age? | 10 | paper's analysis of recall bias in its study? |
| 11 | A. Yes, as do most cancers. | 11 | A. In my report? |
| 12 | Q. Are you aware of any established | 12 | Q. In your report, Doctor. |
| 12 | medical let me start over again. | 13 | A. (Reviews document.) |
| 13 | Are you aware of any established | 14 | In my report, I do not refer to |
| 13 | reliable methodology for determining whether a | 15 | Schildkraut. |
| 14 | . 67 | 16 | MR. HEGARTY: Let me show you |
| 14 15 | specific patient's use of talc in the genital area | 16 | with the original to the show you |
| 14 15 16 | • | 17 | Schildkraut 2016 I marked as Exhibit |
| 14 15 16 | specific patient's use of talc in the genital area caused her ovarian cancer? | l | • |
| 14 15 16 17 | specific patient's use of talc in the genital area caused her ovarian cancer? MR. TISI: Objection. | 17 | Schildkraut 2016 I marked as Exhibit |
| 14 15 16 17 18 | specific patient's use of talc in the genital area caused her ovarian cancer? MR. TISI: Objection. THE WITNESS: I don't believe | 17 18 | Schildkraut 2016 I marked as Exhibit Number 10. |
| 14 15 16 17 18 19 | specific patient's use of talc in the genital area caused her ovarian cancer? MR. TISI: Objection. THE WITNESS: I don't believe there is any documented checklist, if you | 17 18 19 | Schildkraut 2016 I marked as Exhibit Number 10. (Document marked for identification as Harlow Exhibit 10.) |
| 14 15 16 17 18 19 20 | specific patient's use of talc in the genital area caused her ovarian cancer? MR. TISI: Objection. THE WITNESS: I don't believe there is any documented checklist, if you may if I may. | 17 18 19 20 21 | Schildkraut 2016 I marked as Exhibit Number 10. (Document marked for |
| 14 15 16 17 18 19 20 21 | specific patient's use of talc in the genital area caused her ovarian cancer? MR. TISI: Objection. THE WITNESS: I don't believe there is any documented checklist, if you may if I may. It's more of a qualitative | 17 18 19 20 21 | Schildkraut 2016 I marked as Exhibit Number 10. (Document marked for identification as Harlow Exhibit 10.) THE WITNESS: Yep. BY MR. HEGARTY: |
| 14 15 16 17 18 19 20 21 22 | specific patient's use of talc in the genital area caused her ovarian cancer? MR. TISI: Objection. THE WITNESS: I don't believe there is any documented checklist, if you may if I may. It's more of a qualitative assessment of looking at competing risk | 17 18 19 20 21 22 | Schildkraut 2016 I marked as Exhibit Number 10. (Document marked for identification as Harlow Exhibit 10.) THE WITNESS: Yep. |

| Page 16 | 2 Page 164 |
|--|--|
| 1 Q. In fact, you do cite to it in your | 1 A. I believe so, yes. |
| 2 expert report, correct? | 2 Q. There they reported that with regard |
| 3 A. Yes, I do. | 3 to interviews pre-2014, their point estimate was |
| 4 Q. Please turn over to page 412 in this | 4 1.19 with a confidence interval of .87 to 1.63; |
| 5 document. | 5 and their point estimate for post-2014 interviews |
| 6 A. Okay. I just wanted I'm sorry. | 6 was 2.91 with a confidence interval of 1.7 to |
| 7 Page 12? | 7 4.97. |
| 8 Q. 412. | 8 Correct? |
| 9 A. 412. | |
| | 9 A. Yeah. I'm just looking to see if 10 it's in the tables. |
| | |
| , | |
| 12 MR. HEGARTY: 1412. I'm | 12 Table 4 Table 2 on page 1414. |
| 13 sorry. 1412. | 13 A. Yeah. Oh, there it is. Interview |
| 14 THE WITNESS: Hmm. The | 14 date created on '14. Okay. |
| numbers the numbers in mine don't go | 15 Q. Are you with me? |
| that way. | 16 A. I will be in a second. |
| MR. TISI: Oh, you have a | 17 MR. TISI: Take your time and |
| different. | look at it. |
| 19 THE WITNESS: I have a | 19 THE WITNESS: Confidence |
| different copy, but that's okay. | interval greater than '14, less than '14. |
| MR. TISI: I'd like you to | Yes, I now see that. Okay. |
| look if you have it. | 22 BY MR. HEGARTY: |
| THE WITNESS: Well, let me. | 23 Q. The authors found an effect for |
| 24 I'll see. 412? | 24 modification by year that was statistically |
| Page 16 | |
| 1 MR. TISI: 1412. | 1 significant, correct? |
| THE WITNESS: 1412. Okay. | 2 A. They found a they found an |
| The "Materials and Method" section. | 3 association of of 2.91 for any genital use in |
| 4 BY MR. HEGARTY: | 4 those whose interview date was greater than 2014. |
| 5 Q. I'm looking at the "Statistical | 5 Q. I understand, but they also did a |
| 6 analysis" section at the very bottom on the | 6 statistical analysis between the 1.19 |
| 7 right-hand column. | 7 A. Oh, right. |
| 8 A. Yep. | 8 Q and the 2.91 and found that |
| 9 Q. The authors at the end of the | 9 A. Yes. |
| 10 right-hand column recognize that lawsuits were | e 10 Q found the effect by modification |
| 11 filed in 2014 regarding the possible carcinogen | ic 11 by year of interview was statistically |
| 12 effect of of talc and ovarian cancer, and then | 12 significant, correct? |
| 13 they analyzed the data pre- and post-2014, | And if you want to look, it's in the |
| 14 correct? | 14 "Results" section. |
| 15 A. Let me just take a read of that. If | 15 A. No, no, no. I understand. |
| 16 that's okay. | 16 Yes, they reported that. They |
| 17 (Reviews document.) | 17 reported that. That is correct. |
| 18 Yes, I see that. | 18 Q. That analysis indicates that recall |
| 19 Q. Please turn over to the next page | 19 bias had an effect based on year of interview, |
| 20 under the "Results" section, left-hand column | 20 correct? |
| 21 towards the bottom. | 21 A. No, it doesn't. |
| 22 A. Uh-huh. | 22 Q. How does it not show that? |
| 23 Q. Do you see where I'm focusing you | 23 A. It doesn't because we don't know |
| 24 on? | |
| 24 OII: | 24 whether women were recalling after 2014 because of |

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| | D 166 | | D 160 |
|----|---|-----|---|
| 1 | Page 166 litigation, and we also don't know anything abou | f 1 | Page 168 |
| | the dose that those were using in before 2014 or | | report any powder use. When the time period was |
| 3 | _ | l . | limited to women who were interviewed prior to |
| 4 | | | 2014, (i.e., before ongoing lawsuits about genital |
| 5 | ~ | | powder use which had extensive media coverage), |
| 6 | | | the results were attenuated and no longer |
| 7 | MR. TISI: Objection. | l | significant (odds ratios equals 1.19; 95% |
| 8 | <u> </u> | | confidence interval .87 to 1.63). In contrast, a |
| 9 | | l | significant positive association was observed |
| 10 | 1 2 | | |
| 11 | doesn't play a role, but I'm certainly | | among those interviewed after 2014 (odds ratio of 2.91; 95% confidence interval 1.70 to 4.91; |
| 12 | | | |
| 13 | not I'm not considering that recall | | reference 11). These results highlight the |
| 14 | bias is the explanation for it. BY MR. HEGARTY: | | potential for recall bias in case-control studies, |
| 15 | | | especially those conducted after 2013." |
| 1 | Q. You also cite in your report to the | 15 | Do you dispute any of the statements |
| 1 | Davis study; is that correct? | l | that I just read to you? |
| 17 | | 17 | A. I don't dispute any of the |
| 18 | MR. TISI: I'm sorry. What | | statements, but I want I would like to be |
| 19 | 1 0 | | recognized as saying that recall bias is in |
| 20 | | l | this situation is based on any use and, therefore, |
| 21 | I'm going to mark as Exhibit | | those women who perhaps were using it infrequently |
| 22 | • | | might have been more influenced by the knowledge |
| 23 | ` | l | about litigation than than or not. |
| 24 | identification as Harlow Exhibit 11.) | 24 | I mean, I don't I don't believe |
| | Page 167 | | Page 169 |
| 1 | THE WITNESS: Uh-huh. Thank | | let me just say this. |
| 2 | · · · · · · · · · · · · · · · · · · · | 2 | The recall bias does not take into |
| 3 | BY MR. HEGARTY: | | account those who used it consistently for a long |
| 4 | Q. Do you have that in front of you, | l . | period of time. I don't know in this analysis to |
| 5 | | | what extent those before 2014 versus those after |
| 6 | | 6 | 2014 had varying levels of exposure. |
| 7 | MS. PARFITT: Mark, I don't | 7 | And so you're making there's an |
| 8 | • | | assumption being made that the reason for the |
| 9 | • | | recall bias is because of the knowledge of |
| 10 | * | | litigation, and there's no evidence here to show |
| 11 | MR. HEGARTY: Well, it's the | l | that that is, in fact, the truth. |
| 12 | | 12 | These women were not asked whether |
| 13 | | | or not they knew about the litigation in these |
| 14 | * | l | in these studies. |
| 15 | · | 15 | Q. The authors in the paper we're |
| 16 | | | looking at, the Davis paper, did indicate that |
| 17 | 3 | | that could be a possible driver of the difference |
| | BY MR. HEGARTY: | | between the two relative risks; is that correct? |
| 19 | 1 0 | 19 | * |
| 20 | | | specifically where they stated it, but I'm not |
| 21 | Q. The text begins on that page: | | yes to yes, with the restriction of cases in |
| 22 | , | l | control. |
| | genital powder had a 44% higher risk of ovarian | | |
| | concer (adds ratio 1.44: 05% confidence interval | 124 | case-control or cohort study involving talc or |

| | Page 170 | | Page 172 |
|--|--|----|---|
| 1 | ovarian cancer that stratified results as | 1 | "errors in the data collected, principally because |
| 2 | Schildkraut did by date of interview or otherwise | 2 | of errors in recollection or reporting of talc |
| 3 | to try to assess recall bias? | 3 | exposure." |
| 4 | A. Yes. There was a recent article by | 4 | That's what you wrote, correct? |
| 5 | Goodman, I believe, that looked at at a | 5 | A. That's correct. |
| 6 | quantitative bias analysis to see whether or not | 6 | Q. Turning over to pages 257 and 258, |
| | recall bias could influence could be explaining | 7 | E |
| 8 | the association that was observed | 8 | |
| 9 | | 9 | A. Yes. |
| | article. | 10 | |
| 11 | 5 | 11 | A. Yes. |
| 12 | | 12 | Q. You wrote there: |
| | any case-control or cohort studies that where the | | "If exposures to talc were recalled |
| | authors themselves tried to stratify the results | | differently by cases and controls, relative risk |
| | by interview date or otherwise to assess the | | estimates would be distorted." |
| | potential for recall bias as Schildkraut did? | 16 | • |
| 17 | 1 2 | 17 | |
| | remember if there were. | 18 | |
| 19 | | 19 | , , , , , , , , , , , , , , , , , , , |
| | you did with Dr. Hartge. | | there have been new studies since here that have |
| 21 | 3 3 | | evaluated whether or not there is substantial |
| 22 | E | | differential or differential misclassification |
| 23 24 | | | by in case-control studies showing that it had very little effect. |
| 24 | | 24 | • |
| 1 | Page 171 MD. HEGARTY: I'm going to | 1 | Page 173 |
| $\begin{vmatrix} 1 \\ 2 \end{vmatrix}$ | 2 2 | 1 | One was done by I believe I cited them in my report. One was done by Sandra |
| 3 | | | Greenland, and another was done by another person, |
| 4 | | | and I believe it was around fetal fetal death |
| 5 | · · · · · · · · · · · · · · · · · · · | | syndrome. |
| 6 | , | 6 | |
| 1 | BY MR. HEGARTY: | | we're looking at |
| 8 | | 8 | A. Yes. |
| | Dr. Hartge? | 9 | Q in a general sense, "if exposures |
| 10 | - | | to talc were recalled differently by cases and |
| 11 | | | controls, relative risk estimates would be |
| 1 | you? | | distorted." |
| 13 | • | 13 | That is a correct statement? |
| 14 | | 14 | A. I guess it would be. I guess it |
| 15 | 1 6 | | would be a correct statement. |
| 16 | * | 16 | I guess the extent to which it's |
| | Biases in Results From Epidemiological Study." | | distorted and, again, this was a correct |
| 18 | | | statement written in 1994. There has been a lot |
| 19 | · · · · · · · · · · · · · · · · · · · | | of work that has been done to refine the extent to |
| 20 | | | which differential misclassification impacts risk |
| 21 | the current data on talc use and ovarian cancer is | | |
| 22 | all from case-control studies. | 22 | Q. But that statement just standing by |
| 23 | You say that "their limitations stem | 23 | itself is a correct statement? |
| 24 | from three primary sources." The third being | 24 | A. It's what was written in this |

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| 3 A. At that time, it was what we knew. 4 Q. Please turn to the next page. You 5 wrote: 3 THE W. data it says: 5 THE W. | Page 176 ed on doing. RFITT: That is true. ITNESS: Forthcoming oming data from the |
|--|--|
| 2 Q. It was correct at that time? 2 MS. PA 3 A. At that time, it was what we knew. 3 THE W. 4 Q. Please turn to the next page. You 4 data it says: 5 wrote: 5 "Forthco" 6 "Cases could overreport talc use if 6 Nurses Health 7 they were anxious to assign a cause to their 7 analysis, will row 8 cancer or underreport it if they were anxious to 8 talc habits quere 9 avoid providing this information." 9 Until then, reco | RFITT: That is true. ITNESS: Forthcoming |
| 3 A. At that time, it was what we knew. 4 Q. Please turn to the next page. You 5 wrote: 6 "Cases could overreport talc use if 7 they were anxious to assign a cause to their 8 cancer or underreport it if they were anxious to 9 avoid providing this information." 3 THE W. 4 data it says: 5 "Forthcome of the providing the p | ITNESS: Forthcoming |
| 4 Q. Please turn to the next page. You 5 wrote: 6 "Cases could overreport talc use if 7 they were anxious to assign a cause to their 8 cancer or underreport it if they were anxious to 9 avoid providing this information." 4 data it says: 5 "Forthco 7 analysis, will re 8 talc habits quer 9 until then, reco | |
| 5 wrote: 5 "Forthcome of the providing this information." 6 Nurses Health of the providing this information." 7 analysis, will reduce the providing this information." 8 talc habits querify the providing this information." 9 Until then, recome of the providing this information. | oming data from the |
| 6 "Cases could overreport talc use if 6 Nurses Health 7 they were anxious to assign a cause to their 8 cancer or underreport it if they were anxious to 8 talc habits quer 9 avoid providing this information." 9 Until then, reco | oming data from the |
| 7 they were anxious to assign a cause to their 8 cancer or underreport it if they were anxious to 9 avoid providing this information." 7 analysis, will read the talc habits quering the providing this information. | C(11 |
| 8 cancer or underreport it if they were anxious to 9 avoid providing this information." 8 talc habits quer 9 Until then, reco | Study, a prospective cohort |
| 9 avoid providing this information." 9 Until then, reco | |
| , | |
| That is also a true statement, 10 be regarded as | |
| | |
| 11 correct? 11 the talc effect." | |
| 12 A. It is a statement that is written. 12 BY MR. HEGART | |
| | read was a statement that |
| | coming data from the Nurses |
| 15 A. It's possible because it says 15 Health Study," corr | |
| | e I think the idea here |
| The state of the s | een a cohort study that had |
| | ere was the belief that |
| | hen I wrote this, I didn't |
| | he Nurses' Health Study had |
| 21 associations. 21 collected talc at tha | • |
| | ew was that they were |
| | nalysis, and certainly we were |
| 24 regarded as a likely explanation for the talc 24 all excited to see with | hat that would find because it |
| Page 175 | Page 177 |
| 1 effect." 1 was a cohort study. | |
| | ok at the abstract on |
| 3 "In the nine studies, the questions"? Is it that 3 page 1. | |
| 4 paragraph? 4 A. For my? | |
| | 995 publication. |
| 6 end of that paragraph. 6 A. Yes. | |
| | right. 1995. Yes. Got |
| 8 A. Yes. 8 it. | |
| | ok in the middle paragraph. |
| | e we talking of the |
| 11 A. Yes. 11 abstract or? | |
| 12 Q. Then related to the rest of that 12 Q. The abstr | - |
| | es. Uh-huh. |
| | all that the abstract, |
| 15 correct? 15 right? | |
| | yes, yes. Sorry. |
| | n just trying to use the |
| THE WITNESS: I believe it 18 term right. | |
| 19 says 19 A. No, no, n | |
| 20 MR. HEGARTY: Michelle, can we 20 Q. You wrot | |
| | ors conclude that the range |
| | nates from epidemiology, 1 to |
| 23 okay. 23 1.8, is plausible, bu | |
| MR. HEGARTY: I think that's 24 epidemiologic studi | ies, especially prospective |

| | Page 178 | | Page 180 |
|---|---|---|--|
| 1 | investigations are needed." | 1 | MR. HEGARTY: I'm going to |
| 2 | Did I read that correctly? | 2 | mark as Exhibit 13 the 2000 Gertig study. |
| 3 | A. You did. | 3 | (Document marked for |
| 4 | Q. Do you stand behind what you said | 4 | identification as Harlow Exhibit 13.) |
| 5 | back then? | 5 | BY MR. HEGARTY: |
| 6 | A. I do, with the caveat that they are | 6 | Q. Are you familiar with that study? |
| 7 | prospective studies that are specifically designed | 7 | A. I am. |
| 8 | to look at this particular exposure. | 8 | Q. One of the authors was your was |
| 9 | Q. Back in 1995 when you wrote this, | 9 | also a plaintiffs' expert, as you are, and one of |
| 10 | you wrote that prospective investigations are | 10 | your prior colleagues, Dr. Daniel Cramer, correct? |
| 11 | needed to assess this relative risk of 1.0 to 1.8, | 11 | MR. TISI: Objection. |
| 12 | correct? | 12 | THE WITNESS: Well |
| 13 | A. Yes. | 13 | MR. TISI: Objection. He was |
| 14 | Q. You made that statement in part | 14 | not an expert at this time. |
| 15 | because of concern about recall bias, correct? | 15 | Go ahead. |
| 16 | MR. TISI: Objection. | 16 | THE WITNESS: Yeah, I have no |
| 17 | THE WITNESS: Well, that's not | 17 | idea what his subject |
| 18 | the that's not the only reason. | 18 | MR. TISI: Objection to the |
| 19 | If if we have the | 19 | preamble. |
| 20 | opportunity to look at incidence as | 20 | THE WITNESS: Yeah. |
| 21 | opposed to estimating to actually | 21 | MR. TISI: Just ask the |
| 22 | calculate incidence and incidence rate | 22 | question, counsel. |
| 23 | ratios as opposed to estimating the rate | 23 | THE WITNESS: Yeah. Yes, |
| 24 | ratio with odds ratios, we always want to | 24 | Dr. Cramer is an author on this paper. |
| | Page 179 | | Page 181 |
| 1 | be able to do that under the assumption | 1 | BY MR. HEGARTY: |
| 2 | that the study is designed appropriately. | | |
| 4 | | 2 | Q. Looking at the abstract. |
| 3 | BY MR. HEGARTY: | 3 | A. Yes. |
| 3 4 | BY MR. HEGARTY: Q. Understand, but my question was | 3 4 | A. Yes. Q. About two-thirds down, that study |
| 3 4 5 | BY MR. HEGARTY: Q. Understand, but my question was limited to that you made that statement at least | 3 4 | A. Yes. Q. About two-thirds down, that study reported or says: |
| 3 4 5 6 | BY MR. HEGARTY: Q. Understand, but my question was limited to that you made that statement at least in part because of the concern for recall bias, | 3 4 5 6 | A. Yes. Q. About two-thirds down, that study reported or says: "We observed no overall association |
| 3 4 5 6 7 | BY MR. HEGARTY: Q. Understand, but my question was limited to that you made that statement at least in part because of the concern for recall bias, correct? | 3 4 5 6 7 | A. Yes. Q. About two-thirds down, that study reported or says: "We observed no overall association with ever use with ever talc use and epithelial |
| 3 4 5 6 7 8 | BY MR. HEGARTY: Q. Understand, but my question was limited to that you made that statement at least in part because of the concern for recall bias, correct? MR. TISI: Objection. Asked | 3 4 5 6 7 8 | A. Yes. Q. About two-thirds down, that study reported or says: "We observed no overall association with ever use with ever talc use and epithelial ovarian cancer (multivariate relative risk 1.09; |
| 3 4 5 6 7 8 9 | BY MR. HEGARTY: Q. Understand, but my question was limited to that you made that statement at least in part because of the concern for recall bias, correct? MR. TISI: Objection. Asked and answered. | 3 4 5 6 7 8 9 | A. Yes. Q. About two-thirds down, that study reported or says: "We observed no overall association with ever use with ever talc use and epithelial ovarian cancer (multivariate relative risk 1.09; 95% confidence interval 0.86 to 1.37) and no |
| 3 4 5 6 7 8 9 10 | BY MR. HEGARTY: Q. Understand, but my question was limited to that you made that statement at least in part because of the concern for recall bias, correct? MR. TISI: Objection. Asked and answered. THE WITNESS: Yeah. For a | 3 4 5 6 7 8 9 10 | A. Yes. Q. About two-thirds down, that study reported or says: "We observed no overall association with ever use with ever talc use and epithelial ovarian cancer (multivariate relative risk 1.09; 95% confidence interval 0.86 to 1.37) and no increase in risk of ovarian cancer with increasing |
| 3 4 5 6 7 8 9 10 11 | BY MR. HEGARTY: Q. Understand, but my question was limited to that you made that statement at least in part because of the concern for recall bias, correct? MR. TISI: Objection. Asked and answered. THE WITNESS: Yeah. For a number of reasons, recall bias could be | 3 4 5 6 7 8 9 10 11 | A. Yes. Q. About two-thirds down, that study reported or says: "We observed no overall association with ever use with ever talc use and epithelial ovarian cancer (multivariate relative risk 1.09; 95% confidence interval 0.86 to 1.37) and no increase in risk of ovarian cancer with increasing frequency of use." |
| 3 4 5 6 7 8 9 10 11 12 | BY MR. HEGARTY: Q. Understand, but my question was limited to that you made that statement at least in part because of the concern for recall bias, correct? MR. TISI: Objection. Asked and answered. THE WITNESS: Yeah. For a number of reasons, recall bias could be one of many reasons, and particularly for | 3 4 5 6 7 8 9 10 11 12 | A. Yes. Q. About two-thirds down, that study reported or says: "We observed no overall association with ever use with ever talc use and epithelial ovarian cancer (multivariate relative risk 1.09; 95% confidence interval 0.86 to 1.37) and no increase in risk of ovarian cancer with increasing frequency of use." Correct? |
| 3 4 5 6 7 8 9 10 11 12 13 | BY MR. HEGARTY: Q. Understand, but my question was limited to that you made that statement at least in part because of the concern for recall bias, correct? MR. TISI: Objection. Asked and answered. THE WITNESS: Yeah. For a number of reasons, recall bias could be one of many reasons, and particularly for those who are more subject to recall bias | 3 4 5 6 7 8 9 10 11 12 13 | A. Yes. Q. About two-thirds down, that study reported or says: "We observed no overall association with ever use with ever talc use and epithelial ovarian cancer (multivariate relative risk 1.09; 95% confidence interval 0.86 to 1.37) and no increase in risk of ovarian cancer with increasing frequency of use." Correct? MR. TISI: Objection. |
| 3 4 5 6 7 8 9 10 11 12 13 14 | BY MR. HEGARTY: Q. Understand, but my question was limited to that you made that statement at least in part because of the concern for recall bias, correct? MR. TISI: Objection. Asked and answered. THE WITNESS: Yeah. For a number of reasons, recall bias could be one of many reasons, and particularly for those who are more subject to recall bias such as less frequent exposure. | 3 4 5 6 7 8 9 10 11 12 13 14 | A. Yes. Q. About two-thirds down, that study reported or says: "We observed no overall association with ever use with ever talc use and epithelial ovarian cancer (multivariate relative risk 1.09; 95% confidence interval 0.86 to 1.37) and no increase in risk of ovarian cancer with increasing frequency of use." Correct? MR. TISI: Objection. THE WITNESS: That's what |
| 3 4 5 6 7 8 9 10 11 12 13 14 15 | BY MR. HEGARTY: Q. Understand, but my question was limited to that you made that statement at least in part because of the concern for recall bias, correct? MR. TISI: Objection. Asked and answered. THE WITNESS: Yeah. For a number of reasons, recall bias could be one of many reasons, and particularly for those who are more subject to recall bias such as less frequent exposure. MR. HEGARTY: Let's go off the | 3 4 5 6 7 8 9 10 11 12 13 14 15 | A. Yes. Q. About two-thirds down, that study reported or says: "We observed no overall association with ever use with ever talc use and epithelial ovarian cancer (multivariate relative risk 1.09; 95% confidence interval 0.86 to 1.37) and no increase in risk of ovarian cancer with increasing frequency of use." Correct? MR. TISI: Objection. THE WITNESS: That's what they state. |
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|---|---|
| 1 A. Yes. | 1 of just this study that there is an association |
| 2 Q. Under the section "Discussion." | 2 between talc use and epithelial ovarian cancer |
| 3 A. Yes. | 3 MR. TISI: Objection. |
| 4 Q. First paragraph, second sentence, | 4 BY MR. HEGARTY: |
| 5 the authors write: | 5 Q correct? |
| 6 "Because we ascertained talc | 6 MR. TISI: Objection. |
| 7 exposure prior to case diagnosis, the possibility | 7 Misstates testimony. Asked and answered. |
| 8 for recall bias, which has been raised as a | 8 THE WITNESS: Well, actually, |
| 9 potential explanation for previous positive | 9 once they limited it to those who had not |
| 10 findings in case-control studies, is eliminated, | had a tubal ligation or hysterectomy, the |
| 11 and selection bias is reduced." | overall association was 1.15 with a |
| 12 That was a correct statement, | 12 confidence interval of 0.9 to 1.5. |
| 13 correct? | 13 BY MR. HEGARTY: |
| 14 A. No, I don't necessarily believe that | 14 Q. With regard to that answer, staying |
| 15 it was completely eliminated. The Nurses' Health | 15 with page 251. |
| 16 Study was not designed specifically to look at | 16 A. Yes. |
| 17 women they were not enrolled into the study | 17 Q. Right-hand column, middle paragraph. |
| 18 based on exposed or not exposed to talc and, | 18 A. Yes. |
| 19 therefore, all women in that study were required | 19 Q. The authors write: |
| 20 to recall their talc exposure. | 20 "The potential effect of talc on the |
| 21 Q. You said you're familiar with this | 21 ovaries depends on migration of talc fibers |
| 22 study? | 22 through a patent genital tract, and we would, |
| 23 A. Yes. | 23 therefore, expect a stronger association among |
| 24 Q. You cannot conclude just by this | 24 women without a tubal ligation who had used talc. |
| Page 183 | Page 185 |
| 1 study that there is an association between talc | 1 However, no effect modification was seen by |
| 2 use and ovarian cancer, correct? | 2 history of tubal ligation." |
| 3 MR. TISI: Objection. | That's what they concluded, correct? |
| 4 THE WITNESS: No, that's | 4 A. Well, then it goes on to say: |
| 5 not that's not true at all. | 5 "Because we did not have the date of |
| 6 Because as I stated, as I | 6 tubal ligation, some women may have begun talc use |
| 7 stated in my report, that they also | 7 only after tubal ligation, potentially resulting |
| 8 reported an estimated risk ratio of 1.4 | 8 in misclassification of talc use and attenuation |
| 9 for evasive serous ovarian tumors, which | 9 of the relative risks." |
| we know account for the large majority of | 10 Q. But ultimately in their study, as |
| ovarian cancer; and that when the | 11 they report here, when comparing women with tubal |
| 12 analysis was restricted to women who are | 12 ligation and without tubal ligation, they found no |
| 13 45 years of age or older in 1992, they | 13 statistically different results, correct? |
| might represent those who are more highly | 14 MR. TISI: Objection. |
| exposed and maybe possibly have something | |
| to do with asbestos contamination, the | 16 not find a statistically significant |
| association was was present. | difference, but it doesn't but that |
| 18 BY MR. HEGARTY: | doesn't take into account the amount of |
| 19 Q. My question was limited to ovarian | 19 exposure that they had prior to or after |
| 20 cancer. So let me restate it. | 20 the tubal ligation. |
| 21 You cannot conclude on this study | 21 So it's it doesn't if |
| 22 that there is an association let me start over | you're getting at whether if you're |
| 23 again. | 23 getting at the issue of patency, it |
| | |
| You cannot conclude from the results | 24 doesn't adequately assess that. |

Page 188 Page 186 1 BY MR. HEGARTY: 1 But just because the -- the odd --2 Look back again at the abstract. 2 just because the 95 percent confidence interval Q. 3 A. 3 includes 1 does not preclude that the association Particularly the part that I read to 4 is going to be 1 or less. It all really depends Q. 5 you that begins "We observed no overall 5 on the -- on the -- on the width of the confidence 6 association." 6 interval to get a better sense of where the 7 Do you remember that part I read? 7 estimate likely falls. Please turn over to page 18 of your 8 Yes. Yes. 8 Q. Α. 9 Is it your opinion that this study 9 expert report. Q. 10 does show an overall association with ever talc 18 of my expert report. 10 A. 11 use and epithelial ovarian cancer? What we marked as Exhibit Number 5 11 0. It all depends on how you define an 12 12 A. 13 association. There is an elevated risk. It has a 13 Q. At the end of that carryover 14 confidence interval that does include 1. 14 paragraph just before the "Case-control studies 15 O. Understood. 15 are inferior to cohort study" section. Are you with me? 16 My question, though, is: Is it your 16 17 opinion that this study does show an association 17 Yeah. Let me just see. This is A. 18 with ever talc use and epithelial ovarian cancer? 18 recall bias. Uh-huh. 19 I would say, yes, it does when you 19 O. It is in the recall bias section, 20 take into account the refinement of the exposure 20 correct? 21 assessment. 21 A. Yes, uh-huh. Uh-huh. 22 So in your opinion, the statement 22 Q. You say at the end of that section: 23 they make, "We observed no overall association 23 "In our opinion, daily use of talc 24 with ever talc use and epithelial ovarian cancer," 24 over long periods or decades is unlikely to be Page 187 Page 189 1 is not correct? 1 recalled inaccurately." 2 MR. TISI: Objection. 2 Do you see where I'm reading? 3 THE WITNESS: It's not a yes 3 Actually, hold on a second. 4 or no type of response. It's how one 4 (Reviews document.) 5 might interpret it. 5 Yes. Okay. "In our opinion." Yes. 6 They interpreted it as showing 6 Go ahead. 7 no association based on a statistical cut Is it your opinion that reporting of 8 point. 8 two times a week is also unlikely to be recalled 9 My view is to look at the 9 inaccurately? 10 entire body of the article to try to get 10 A. Again, you're trying to make a 11 a sense of whether or not there is an 11 dichotomy here. 12 association under the appropriate exposed Certainly daily use of talc over 13 situations. 13 long periods of time is not likely to be recalled 14 BY MR. HEGARTY: 14 inaccurately. For purposes of your report and your 15 I cannot speak to one -- to once a 16 testimony in this case, how are you defining the 16 week or -- or once a month, but certainly the 17 phrase "an association"? What's your definition? 17 amount of recall bias, in my view, would increase 18 An association in my -- would be my 18 with the -- with a decrease in frequency of using 19 definition that shows that the risk estimate is 19 it. 20 more likely to be positive than not. 20 Have you spoken with any of your 21 When the odds -- when the odds ratio 21 colleagues at Boston University about your work on 22 or relative risk does not include 1, then there is 22 this litigation? 23 a much more certainty that the true association is 23 A. 24 greater than 1. 24 Q. Have you told any of your colleagues

| Page 190 | Page 192 |
|---|---|
| 1 at Boston University your opinions in this | 1 organizations or societies about your opinions in |
| 2 litigation as set out in your report? | 2 this case? |
| 3 A. No, I have not. | 3 A. I have not. |
| 4 Q. Have you gone over to talk to any of | 4 Q. Have you shared your opinions in |
| 5 the gynecologists and gynecologic oncologists at | 5 your report as to talc and ovarian cancer in any |
| 6 the Boston University Chobanian & Avedisian | 6 written peer-reviewed publication? |
| 7 A. (Laugh). Avedisian. | 7 MR. TISI: Objection. |
| 8 Q Medical School of your opinions | 8 THE WITNESS: Yeah. I don't |
| 9 in your report? | 9 believe I have. |
| 10 A. No, I have not. | 10 BY MR. HEGARTY: |
| 11 Q. Have you talked to anyone at the | 11 Q. Have you shared your opinions set |
| 12 Boston University BMC Cancer Center about your | 12 out in your report at any symposia or conference? |
| 13 opinions in this report? | 13 A. No. |
| 14 A. No, I have not. | 14 Q. And as I mentioned just a moment |
| 15 Q. Have you told | 15 ago, your report has not been peer-reviewed, |
| 16 MR. TISI: I assume other than | 16 correct? |
| 17 Dr. Rothman, right? | 17 A. That is correct. |
| 18 MR. HEGARTY: Well, I'll let | 18 Q. Has any medical society or |
| 19 him answer. | 19 organization reached out to you about talc and |
| 20 MR. TISI: Well, I mean, I'm | 20 ovarian cancer? |
| 21 assuming that that's | 21 A. No. |
| 22 BY MR. HEGARTY: | 22 Q. Can you cite to any U.S. scientific |
| 23 Q. Well, Dr. Rothman, is he at the BU | 23 or medical group, entity, or organization who has |
| 24 BMC Cancer Center? | 24 made the statement that talc use can cause ovarian |
| | |
| Page 191 | Page 193 |
| Page 191 1 A. No. He's in the School of Public | Page 193 1 cancer? |
| | _ |
| 1 A. No. He's in the School of Public | 1 cancer? |
| A. No. He's in the School of Public Health with me. | 1 cancer? 2 MR. TISI: Objection. |
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|----|--------------|--------------------------------------|----|-----------|--|
| | | Page 194 | | | Page 196 |
| 1 | 1 | Do you recall that? | 1 | Q. | Did you note when you read it the |
| | | Yes, I do. | 2 | _ | ure or declaration of conflict of interest |
| 3 | | You also cite in your report to a | 3 | | ottom of the first page? |
| 2 | _ | sorry to a to a study or article | 4 | A. | No, I didn't. |
| 5 | • | n from 2020. | 5 | Q. | If you look at the bottom on the |
| 1 | • | Do you recall that article? | | _ | nd side, do you see where it says as it |
| 7 | | Where do I cite that? | | | to certain of the authors, including |
| 8 | Q. | You include it in your references in | | | lman well, let me start over again. |
| 9 | ~ | and you cite to it in your report. | 9 | υ | As it relates to Dr. Egilman, that |
| 10 | | Do you see that? | 10 | he serve | es as an expert witness in litigation at |
| 11 | A. | Oh. Oh, right. Yes. Yes, yes, | | | uest of people who are injured as a result |
| 12 | 2 yes. | • | | _ | g talcum powder? |
| 13 | - | Particularly in your report on | 13 | A. | Right. |
| 14 | page 9. | • • | 14 | Q. | Have you seen that before right now? |
| 15 | 5 A. | Yeah, yeah, Yes. | 15 | A. | Yeah. Right. Yes. |
| 16 | 5] | 'm just looking where I cited it. | 16 | Q. | Had you seen that before right now? |
| 17 | Yes. | | 17 | A. | Oh, I probably saw it, but I don't |
| 18 | } | MR. HEGARTY: And just so you | 18 | necessa | rily evaluate literature based on based |
| 19 | can f | amiliarize yourself with what I'm | 19 | on this. | |
| 20 |) askin | g you, I'll mark as Exhibit 14 the | 20 | Q. | Do you see just below that part |
| 21 | Steff | en article. | 21 | where i | t says: |
| 22 | 2 | (Document marked for | 22 | | "Dr. Egilman, Dr. Rigler and |
| 23 | | ification as Harlow Exhibit 14.) | | Dr. Lor | ngo report payments from lawyers |
| 24 | BY MR. | HEGARTY: | 24 | A. | Yes, I see it. |
| | | Page 195 | | | Page 197 |
| 1 | Q. | That's the article | 1 | Q. | related to the submitted work"? |
| 2 | 2 A. | Yeah. | 2 | A. | Yes, I see it. |
| 3 | _ | you reference in your report, | 3 | Q. | Did you consider that funding |
| 4 | correct? | | 4 | statemer | nt in evaluating this paper? |
| 5 | | Just trying to see where I reference | 5 | A. | No, I didn't. |
| 1 | this article | e. | 6 | Q. | Is it appropriate when you consider |
| 7 | Q. | Please look over on page 9 in | 7 | a paper l | like this to consider the source of |

Do I have it as reference 9 on my --

I'm looking at page 9 at the top.

And reference 7 is Steffen's?

Right. Right, right, right. Got

Did you read this article?

I marked as Exhibit Number 14 the

Yes. Yes, yes, yes.

And I'm --

Oh, yeah. It's 7. Oh, yeah. Okay.

10 let me -- let me just take a second. Hold on. Is

ave you seen that before right now? eah. Right. Yes. ad you seen that before right now? h, I probably saw it, but I don't evaluate literature based on -- based o you see just below that part vs: r. Egilman, Dr. Rigler and report payments from lawyers -es. I see it. Page 197 elated to the submitted work"? es, I see it. d you consider that funding evaluating this paper? , I didn't. it appropriate when you consider this to consider the source of 8 funding and whether they're -- the authors are 9 expert witnesses in litigation? 10 I think it is important to consider 11 it as one consideration, but I believe in this 12 situation where -- where basically they are doing 13 a laboratory assessment, I'm less concerned about 14 whether or not that would have influenced the 15 fundings. 16 O. The only authorities that you cite 17 for the statements in your report that talcum 18 powder contains asbestos are Dr. Longo and 19 Rigler's report and the Steffen's article, 20 correct? 21 MR. TISI: Objection. 22 THE WITNESS: Well, it's in my 23 report, but in all my writings that I've 24 published, I've -- I've referenced many

8 reference 7 at the top.

11 it 7 or is it 9?

Q.

A.

Q.

A.

Q.

A.

O.

A.

Q.

A.

Yes.

21 Steffen's article.

14 Got it. Got it. Yes.

12

13

15

16

17

18

20

22

23

24

19 it.

| | D. 100 | | D 000 |
|---------------|---|-------|--|
| 1 | Page 198 other articles. | 1 | Page 200 MR. HEGARTY: But let's not |
| $\frac{1}{2}$ | BY MR. HEGARTY: | 2 | get into discussion. |
| 3 | Q. And I'm not asking about your other | 3 | MR. TISI: Okay. |
| | writings. | - | BY MR. HEGARTY: |
| 5 | A. I understand that. | 5 | Q. How much time? Do you need more |
| 6 | Q. My question is specific | | time? |
| 7 | specifically limited to your report. | 7 | A. I would need more time to look |
| 8 | In your report | · ' | specifically at every word that I wrote to see if |
| 9 | A. Yes. | | there are other locations other places where I |
| 10 | Q the only authorities that you | | cited the issue of talc the issue of asbestos |
| | cite to for your statements that talcum powder, | | being seen in talc examples. |
| | including Johnson & Johnson talcum powder, | 12 | Q. And if we have time, we can go back |
| | contains asbestos are the Rigler and Longo | | to this question. |
| | materials and the Steffen's article, correct? | 14 | A. Okay. |
| 15 | MR. TISI: Objection. | 15 | Q. With regard to your citation to the |
| 16 | Misstates. | | report by Dr. Longo and Rigler, did you read the |
| 17 | THE WITNESS: So I would have | | entirety of that report? |
| 18 | to look. In this particular paragraph, | 18 | A. I would hope I read the most salient |
| 19 | but there might be other locations in the | | components of it. (Laugh). |
| 20 | report where I had referred to that, and | 20 | Q. Well, can you tell me today |
| 21 | I would have to look carefully about | 21 | A. Yeah. |
| 22 | that. | 22 | Q if you read the entirety of it |
| 23 | BY MR. HEGARTY: | 23 | from page to page? |
| 24 | Q. How long would that take you to | 24 | A. Yes. |
| | Page 199 | | Page 201 |
| 1 | look? | 1 | Q. As to Dr. Longo and Rigler's report, |
| 2 | A. Just give me a minute. Let me see | 2 | did you make a request for that report or was that |
| 3 | if they're listed, if I had things. | 3 | sent to you? |
| 4 | Okay. I'll I'll I'll agree | 4 | A. That was sent to me. |
| 5 | that that's these are the this is the | 5 | Q. Are you aware that there are more |
| 6 | report. | | there are other experts who have issued reports |
| 7 | MR. TISI: Objection. | | and who have testified with regard to the testing |
| 8 | THE WITNESS: This is the | 8 | of talcum powder for asbestos? |
| 9 | evidence. | 9 | MR. TISI: In the MDL and New |
| 10 | MR. TISI: Actually all | 10 | Jersey, or no? |
| 11 | right. I don't want you to feel rushed. | | BY MR. HEGARTY: |
| 12 | Okay? If you need to look, I mean, there | 12 | Q. We'll limit it to the MDL and New |
| 13 | is fine. I'll clean it up. | | Jersey cases. |
| 14 | THE WITNESS: No, that's | 14 | A. Yeah. No, I'm not aware of that. |
| 15 | fine. | | Except that I'm aware of articles in the |
| 16 | MR. TISI: I mean, you know | | scientific literature that have been published |
| 17 | that that's | 17 | |
| 18 | MR. HEGARTY: You can ask that | | asbestos in each decade for the last 40 years. |
| 19 | question. | 19 | Q. Did you ask or make a request for |
| 20 | MR. TISI: You know that | 20 | defense expert reports addressing the issues of |
| 21 | that's not true. You can't | | asbestos testing for talc and asbestos in talc? |
| 22 | MR. HEGARTY: I don't know | 22 | MR. TISI: Objection. In the |
| 23 | that that's not true. MR. TISI: Really? | 23 24 | MDL or in New Jersey where he's designated? |
| 24 | | | |

| | Page 202 | | Page 204 |
|---|---|--|--|
| 1 | MR. HEGARTY: Or anywhere in | 1 | extent that there's been any reports by |
| 2 | any situation. | 2 | the defendant in this litigation. |
| 3 | MR. TISI: Well, there have | 3 | BY MR. HEGARTY: |
| 4 | been none in any case in which he's been | 4 | Q. You can answer. |
| 5 | involved. So until you name them, you | 5 | MR. TISI: You can answer. |
| 6 | can't expect him to know them. | 6 | THE WITNESS: No, I have not. |
| 7 | MR. HEGARTY: I didn't ask him | 7 | BY MR. HEGARTY: |
| 8 | that. I just asked him | 8 | Q. As to Dr. Longo's report, it was not |
| 9 | MR. TISI: Well, no. I mean, | 9 | a peer-reviewed document, correct? |
| 10 | come on. | 10 | A. I'm not sure whether it was |
| 11 | MR. HEGARTY: Chris, listen to | | peer-reviewed or not. |
| 12 | my question. I'll ask the question | 12 | Q. Do you have you ever met |
| 13 | again. | | Dr. Longo or Dr. Rigler? |
| 14 | MR. TISI: That's totally | 14 | A. No. |
| 15 | unfair. | 15 | Q. Do you know anything about their |
| 16 | MR. HEGARTY: Listen to my | | training, education, and experience? |
| 17 | question. | 17 | A. I do not. |
| | • | 18 | Q. Do you know how much money Dr. Longo |
| 19 | Q. My question is: Did you ask for any | 1 | has made testifying for plaintiffs in talcum |
| | expert reports that have been issued from | | powder litigation? |
| | attorney from experts representing or | 21 | A. I do not. |
| | testifying on behalf of Johnson & Johnson that | 22 | Q. Is that something you're interested |
| | respond or address the issues of asbestos in talc | | in knowing? |
| | in particular as it relates to testing of talc for | 24 | A. No. |
| | Page 203 | | Page 205 |
| 1 | asbestos? | 1 | Q. Do you know how many times that |
| 2 | MR. TISI: Your question | 2 | Dr. Longo has testified for plaintiffs that |
| 3 | assumes facts not in evidence in this MDL | 1 | |
| | | 3 | products contain asbestos, that is, talcum powder |
| 4 | or in New Jersey. So I object. | | , , , |
| 4 5 | or in New Jersey. So I object. BY MR. HEGARTY: | | products contain asbestos based on his testing? |
| - | BY MR. HEGARTY: | 4 | products contain asbestos based on his testing? A. No, I do not know. I do not know. |
| 5 | BY MR. HEGARTY: | 4 5 6 | products contain asbestos based on his testing? |
| 5 | BY MR. HEGARTY: Q. You can answer. | 4 5 6 | products contain asbestos based on his testing? A. No, I do not know. I do not know. Q. Have you ever visited Dr. Longo's |
| 5 6 7 | BY MR. HEGARTY: Q. You can answer. A. I would not have known whether those existed or not. So I would not have known to ask. | 4 5 6 7 | products contain asbestos based on his testing? A. No, I do not know. I do not know. Q. Have you ever visited Dr. Longo's labs? A. No. |
| 5 6 7 8 9 | BY MR. HEGARTY: Q. You can answer. A. I would not have known whether those existed or not. So I would not have known to ask. Q. If such reports and testimony exist, | 4 5 6 7 8 9 | products contain asbestos based on his testing? A. No, I do not know. I do not know. Q. Have you ever visited Dr. Longo's labs? A. No. Q. Is it true, Doctor, that you're not |
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| 5 6 7 8 9 10 11 12 13 14 15 16 17 18 | BY MR. HEGARTY: Q. You can answer. A. I would not have known whether those existed or not. So I would not have known to ask. Q. If such reports and testimony exist, are you interested in reviewing them? A. Yes. MR. TISI: When they become available. BY MR. HEGARTY: Q. Have you reviewed Dr. Longo or Dr. Rigler's testimony in any case involving talcum powder and either ovarian cancer or mesothelioma? | 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 | products contain asbestos based on his testing? A. No, I do not know. I do not know. Q. Have you ever visited Dr. Longo's labs? A. No. Q. Is it true, Doctor, that you're not knowledgeable about let me start over again. It is true, Doctor, that you are not knowledgeable about the reasonableness of the processes and procedures of any of the tests that Dr. Longo and Rigler conducted on any talc product, correct? A. I do not know what their parameters were in their laboratory testing. Q. You have no |
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| | Page 206 | | Page 208 |
|--|---|--|--|
| 1 | A. Actually, reliable means that it is | 1 | So, and talc itself has been shown to cause an |
| 2 | means it's been shown over and over again. | 2 | inflammatory process. |
| 3 | That's what reliability means, and the fact that | 3 | |
| | there have been a number of articles in the | 4 | |
| 5 | scientific literature by well before any of the | 5 | · |
| | litigation began showing that there is the | 6 | |
| | potential for asbestos contamination, to me that | 7 | • |
| 8 | suggests that the work that's done by Longo is | 8 | - |
| | is reliable. | 9 | |
| 10 | Q. Do you know what a cleavage fragment | 10 | in talc as relate to your causation opinions? |
| 11 | is? | 11 | A. No. For one thing, you just don't |
| 12 | A. No. | 12 | know. |
| 13 | Q. Can tremolite come in an asbestiform | 13 | Q. There are six plaintiffs whose cases |
| 14 | and non-asbestiform mineral type? | 14 | we are working up in the MDL and two plaintiffs in |
| 15 | A. I am not an expert in that area. | | the in the New Jersey litigation. |
| 16 | Q. You're not an expert in asbestos? | 16 | |
| 17 | A. I would not call I am an expert | 17 | me after I'm finished whether you know any of |
| 18 | in reviewing epidemiologic research, and I have | | these women. |
| 1 | the ability to look at research that has been in | 19 | Lynda Bondurant, Escalina Roussa, |
| 1 | the peer-reviewed literature and make conclusions | 20 | Hilary Converse, Carter Judkins, Tamara Newsome, |
| | as to whether I believe they are scientifically | | Anna Gallardo. And I'm not sure of the first |
| | strong or not. | 22 | names. I can look them up. Ms. Karl and |
| 23 | Q. Do you have an opinion as to whether | | Ms. Moldurano. |
| 24 | non-asbestiform tremolite can cause ovarian | 24 | Are any of those names familiar to |
| | D 405 | | |
| | Page 207 | | Page 209 |
| 1 | Page 207 cancer? | 1 | Page 209 you? |
| 1 2 | | 1 2 | you? |
| | cancer? | | you? A. Not that I'm aware of, no. |
| 2 | cancer? A. I don't have an opinion. | 2 | you? A. Not that I'm aware of, no. Q. Do you have any information about |
| 3 | cancer? A. I don't have an opinion. Q. Sitting here today, can you name the | 2 3 | you? A. Not that I'm aware of, no. Q. Do you have any information about any of those women with regard to the type of |
| 3 4 | cancer? A. I don't have an opinion. Q. Sitting here today, can you name the six types of asbestos? | 2 3 4 | you? A. Not that I'm aware of, no. Q. Do you have any information about any of those women with regard to the type of ovarian cancer that they have? |
| 2 3 4 5 | cancer? A. I don't have an opinion. Q. Sitting here today, can you name the six types of asbestos? A. No. | 2 3 4 5 | you? A. Not that I'm aware of, no. Q. Do you have any information about any of those women with regard to the type of ovarian cancer that they have? A. No. |
| 2 3 4 5 6 7 | cancer? A. I don't have an opinion. Q. Sitting here today, can you name the six types of asbestos? A. No. Q. Do you know the most common the | 2 3 4 5 6 | you? A. Not that I'm aware of, no. Q. Do you have any information about any of those women with regard to the type of ovarian cancer that they have? A. No. Q. Do you know where they live? |
| 2 3 4 5 6 7 | cancer? A. I don't have an opinion. Q. Sitting here today, can you name the six types of asbestos? A. No. Q. Do you know the most common the most commonest asbestos that was used | 2 3 4 5 6 7 | you? A. Not that I'm aware of, no. Q. Do you have any information about any of those women with regard to the type of ovarian cancer that they have? A. No. Q. Do you know where they live? A. No. |
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| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 | cancer? A. I don't have an opinion. Q. Sitting here today, can you name the six types of asbestos? A. No. Q. Do you know the most common the most commonest asbestos that was used commercially? A. That's not where I spend my time reviewing the scientific literature. The whole idea behind my review of the scientific literature was to determine whether there was a biologically plausible explanation fo the epidemiologic association, and the fact that there is evidence that there could be asbestos contamination makes adds one more source of biological plausibility to it. Q. Is asbestos contamination of talc necessary for your causation opinions in this case? | 2 3 4 5 6 7 8 9 10 11 12 r 13 14 15 16 17 18 19 20 | A. Not that I'm aware of, no. Q. Do you have any information about any of those women with regard to the type of ovarian cancer that they have? A. No. Q. Do you know where they live? A. No. Q. Do you know do you have any knowledge of any of the women whose names I just mentioned use of talcum powder? A. No. Q. In particular, do you know how long any of them used talcum powder? A. No. Q. Do you know the frequency that they used talcum powder? A. No. Q. Do you know the volume of talcum powder that they used? A. No. |
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| Page 21 | Page 212 |
|---|---|
| 1 Q. Do you know of any testing for | 1 A. That is correct. |
| 2 asbestos that was done as to any talcum powde | Q. Do you have any forthcoming |
| 3 product they claim to have used? | 3 publications regarding talcum powder use and |
| 4 A. No. | 4 ovarian cancer? |
| 5 Q. Are you going to tell the judge and | 5 A. No. |
| 6 jury in the cases we're talking about today that | 6 Q. If you had any such publications or |
| 7 you know the cause of each of these women's | 7 if you have any such let me start over again. |
| 8 ovarian cancer? | 8 If you have any publications in the |
| 9 MR. TISI: Objection. Can I | 9 future, would you disclose as a conflict of |
| help you out and say he's not going to be | 10 interest your work in this litigation? |
| asked any questions about case-specific. | 11 A. Yes, I would if it was relevant to |
| 12 I'm not going to ask him. | 12 this particular exposure and outcome. |
| MR. HEGARTY: Let him answer. | 13 Q. Are you working on any articles or |
| 14 THE WITNESS: I can't answer | 14 studies that pertain to talcum powder use and |
| that. I have no idea what I'm going to | 15 ovarian cancer? |
| say. I have no idea at that point with | 16 A. I am not. |
| 17 respect to that issue.18 BY MR. HEGARTY: | 17 Q. Are you working on any articles or 18 studies about asbestos and ovarian cancer? |
| | |
| Q. Well, let me ask it.MR. TISI: He has not been | 19 A. No.20 Q. Now, with regard to the report that |
| 21 designated as a case-specific expert. | 20 Q. Now, with regard to the report that 21 you and Dr. Rothman prepared in this litigation, |
| 22 MR. HEGARTY: Let me re-ask | 22 which we have been talking about this morning that |
| 23 the question. | 23 I marked as Exhibit Number 5 |
| 24 BY MR. HEGARTY: | 24 A. Uh-huh. |
| Page 21 | Page 213 |
| 1 Q. Sitting here today, is it your | 1 Q is it correct that all the |
| 2 intent to tell the judge and the jury in this case | 2 opinions that you intend to offer in this |
| 3 that you know what caused each of the women | s 3 litigation are set out in this report? |
| 4 ovarian cancer whose names I read to you? | 4 A. I believe so. Pending I believe at |
| 5 A. No. I all of what my | 5 the end of the report we had the we have the |
| 6 expertise is at the population level. I cannot | 6 right to look at additional information that |
| 7 I cannot definitive I will not definitively | 7 becomes available or provided to us. But barring |
| 8 state that I don't know anything about these | 8 that, my opinions are in this report. |
| 9 women. I just don't know anything about these | |
| 10 women. | "We reserve the right to amend this |
| 11 Q. Sitting here today, you don't | 11 report." |
| 12 represent Boston University, correct?13 A. That's correct. | 12 You have not issued an amended |
| | 13 report, correct? 14 A. I have not. |
| 14 Q. You don't speak for Boston15 University or any entity in this case, correct? | 14 A. I have not. 15 Q. Have any of your opinions set out in |
| 16 A. I do not. | 16 this report changed or modified since November |
| 17 Q. You're not speaking for any | 17 2023? |
| 18 scientific organization or body? | 18 A. No. |
| 19 A. No, I am not. | 19 Q. All the materials on which you |
| 20 Q. You're not speaking for any | 20 rely let me start over again. |
| 21 regulatory group or agency? | 21 All the materials on which you |
| 22 A No. | 22 intend to reference in providing your opinions or |

54 (Pages 210 - 213)

22 intend to reference in providing your opinions are

23 set out in your report or in the Materials

24 Considered list, correct?

You're not speaking for anyone but

A.

Q. 24 yourself?

22

23

| They may become. They may be may build in that to be exclusive. There are the date report and now, and I can go the and every one of them. They may be | | Page 214 Page 216 |
|--|---|---------------------------------------|
| THE WITNESS: Well, I mean, again MR. TISI: Additional additional information one second. MR. HEGARTY: Please let him answer the question. MR. TISI: No, let me. Objection. He reserves the right and we reserve the right to ask him not only to comment on any expert report by the defendants, which has not been they have not been provided yet, but also to respond to information that becomes available and have become available since the time of his report including, for example I mean, there are things like the recent EPA rule, for example. There are things that have become available, and I expect him to be able to give opinions based upon those. There are thing here today, are all the materials you intend to refer to in providing you opinions in this case set out in your report teither at the end of the report or in the Materials Considered list? A. No, I can't say that that's the case and Q. Well, what materials I'm sorry. G. Can you answer my questin A. Well, the recent EPA report that came out that specified talc asbestos as being in formation might come out from the scientific literature. MR. HEGARTY: A. A. Again, I don't know. MR. TISI: Let me just of that to be exclusive. There are that to that to be exclusive. There are that that to be exclusive. There are that that to be exclusive. There are that that we have provided to him or gotten on his own since the date that we have provided to him or gotten on his own since the date report and now, and I can go the that we have provided to him or gotten on his own since the date report and now, and I can go the and every one of them. I doubt you want that to anything to be seen as we are lin him to November of 2023, and I that, but I do not want that to anything to be seen as we are lin him to November of 2023, and I that, but I do not want that to anything to be seen as we are lin him to November of 2023, and I that, but I do not want that to that we have provided to him or gotten on his own sance that we have provided to him or | MR. TISI: Object. Objection. | |
| THE WITNESS: Well, I mean, again — 4 again — 5 MR. TISI: Additional — 6 additional information — one second. 7 MR. HEGARTY: Please let him 8 answer the question. 8 MR. TISI: No, let me. 10 Objection. He reserves the 11 right and we reserve the right to ask him 12 not only to comment on any expert report 13 by the defendants, which has not been—14 they have not been provided yet, but also 15 to respond to information that becomes available and have become available since 17 the time of his report including, for 18 example — I mean, there are things like 19 the recent EPA rule, for example. 10 There are things that have 12 become available and will continue to 22 become available and will continue to 23 able to give opinions based upon those. 24 BY MR. HEGARTY: 1 Q. Let me ask my question. 2 Sitting here today, are all the 3 materials you intend to refer to in providing your 4 opinions in this case set out in your report 5 either at the end of the report or in the 6 Materials Considered list? 7 A. No, I can't say that that's the case 8 and — 9 Q. Well, what materials — I'm sorry. 10 Go ahead. 11 A. Well, the recent EPA report that 12 came out that specified talc — asbestos as being 13 a cause for ovarian cancer is something that I 1 might refer to, and I don't know what other 15 information might come out from the scientific 16 literature. 17 So I can't affirmatively say that 18 the only information that I might say in the 18 | , | |
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| 4 opinions in this case set out in your report 5 either at the end of the report or in the 6 Materials Considered list? 7 A. No, I can't say that that's the case 8 and 9 Q. Well, what materials I'm sorry. 10 Go ahead. 11 A. Well, the recent EPA report that 12 came out that specified talc asbestos as being 13 a cause for ovarian cancer is something that I 14 might refer to, and I don't know what other 15 in providing your opinions in this case? 6 MR. TISI: Objection for the 7 reasons I stated. 8 You may answer. 9 THE WITNESS: I don't know what other references or documents might become available at the time. 11 can't say that I know of something a right now. 12 right now. 13 right now. 14 MR. HEGARTY: Let's go or record. 15 record. 16 (Whereupon, at 1:04 p.m., a luncheon recess was taken.) 18 the only information that I might say in the | | |
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| 16 literature. 16 (Whereupon, at 1:04 p.m., a 17 So I can't affirmatively say that 17 luncheon recess was taken.) 18 the only information that I might say in the 18 | | |
| 17 So I can't affirmatively say that 17 luncheon recess was taken.) 18 the only information that I might say in the 18 | ight refer to, and I don't know what other | |
| 18 the only information that I might say in the 18 | ight refer to, and I don't know what other formation might come out from the scientific | |
| | ight refer to, and I don't know what other formation might come out from the scientific erature. | |
| 17 TULUIC WOULD COINC HOLD ALUCICS AND COINCIL III + 19 | ight refer to, and I don't know what other formation might come out from the scientific erature. So I can't affirmatively say that | |
| 20 this report. | ight refer to, and I don't know what other formation might come out from the scientific erature. So I can't affirmatively say that e only information that I might say in the | |
| | ight refer to, and I don't know what other formation might come out from the scientific erature. So I can't affirmatively say that e only information that I might say in the ture would come from articles and content in | |
| | ight refer to, and I don't know what other formation might come out from the scientific erature. So I can't affirmatively say that e only information that I might say in the ture would come from articles and content in is report. | |
| 23 any other authority, publication, or otherwise you23 | ight refer to, and I don't know what other formation might come out from the scientific erature. So I can't affirmatively say that e only information that I might say in the ture would come from articles and content in is report. Q. Other than the EPA report you | , sitting note today, or 22 |
| 24 intend to refer to as of today in discussing or 24 | ight refer to, and I don't know what other formation might come out from the scientific erature. So I can't affirmatively say that e only information that I might say in the ture would come from articles and content in its report. Q. Other than the EPA report you ferenced, do you know, sitting here today, of | lication, or otherwise vol(23 |

| | Page 218 | | Page 220 |
|----|---|--|---|
| 1 | AFTERNOON SESSION | 1 A. I reviewed yes, there are review | s |
| 2 | (1:40 p.m.) | 2 that I I cited in my previous publications | |
| 3 | BERNARD L. HARLOW, PHD | 3 and but, again, I was I was focusing on | the |
| 4 | called for continued examination and, having been | 4 epidemiologic human studies with respect to | coming |
| 5 | previously duly sworn, was examined and testified | 5 up with my opinions. | |
| 6 | further as follows: | 6 Q. Do you agree that you did not | |
| 7 | EXAMINATION (CONTINUED) | 7 specifically cite to any animal study in your | |
| 8 | MR. HEGARTY: We are back on | 8 report? | |
| 9 | the record after a short lunch break. | 9 A. I | |
| 10 | | MR. TISI: Objection. | |
| 11 | Q. Doctor, do you agree that before | 11 THE WITNESS: I I can't be | |
| | offering opinions in a case like this, where you | certain of that, but it certainly did not | |
| | will be heard by and relied upon by a judge and a | weigh in on my conclusions. | |
| | jury, you should have completed a comprehensive | 14 BY MR. HEGARTY: | _ |
| | analysis of the literature that was available to | 15 Q. Did you do a comprehensive revie | w of |
| | you about the subject matter of your opinions? | 16 all the cell study literature involving talcum | |
| 17 | A. Yes. | 17 powder? | |
| 18 | Q. Have you ever offered in any public | 18 A. No. | |
| 1 | | 19 Q. You did not refer to any cell | 1 |
| 20 | Have you ever offered in any | 20 studies where cells are or talc has been appli | ea |
| | publication opinions on any subject matter that would be read and relied upon by your peers and | 21 to cells in your report, correct?22 A. That's correct. | |
| | others that was not based on a comprehensive | 23 Q. Did you do a comprehensive analy | 70 1 0 |
| | analysis of the literature that was available to | 24 of all the publications that have discussed | 515 |
| - | <u> </u> | 21 of all the paoreations that have discussed | D 221 |
| 1 | Page 219 you on the subject matter of the whatever you were | 1 asbestos and ovarian cancer? | Page 221 |
| | discussing? | 2 A. No, I did not. | |
| 3 | A. No. | 3 Q. As to the IARC 2012 Monograph, | which |
| 4 | Q. With regard to what you reviewed for | 4 you do reference in your report | *************************************** |
| | your opinions in your report, did you do a | 5 A. Uh-huh. | |
| | comprehensive analysis of all the animal studies | 6 Q did you read that monograph wh | nen |
| 7 | involving talcum powder? | 7 it came out initially? | |
| 8 | MR. TISI: Objection. Vague. | 8 A. No. | |
| 9 | THE WITNESS: I reviewed some | 9 Q. Did you read that monograph befo | re |
| 10 | of the animal models, but the problem is | 10 you started working on your expert report? | |
| 11 | that it's it's difficult because most | 11 A. No. | |
| 12 | of the studies have been done in mice and | 12 Q. Did you read the entirety of that | |
| 13 | rats, and they have different anatomical | 13 monograph in connection with preparing you | ur expert |
| 14 | features that are dissimilar from that | 14 report? | |
| 15 | with women, such as a bursa sac that | 15 A. I read parts of it. | |
| 16 | encloses the ovaries. | 16 Q. That monograph referred to a num | ber |
| 17 | BY MR. HEGARTY: | 17 of studies that looked at asbestos exposure a | nd |
| 18 | Q. In connection with preparing your | 18 ovarian cancer. | |
| | report in this case, did you review the studies of | 19 Did you pull the individual studies | |
| | those animal models? | 20 and read them | |
| 21 | A. No, I didn't. | 21 A. I didn't. | |
| 22 | Q. So any review of the animal studies | 22 Q that were referenced in the | |
| | that you referenced was before you were contacted | 23 monograph? | |
| 24 | by plaintiffs' counsel? | A. No, I didn't. Again, that goes | |

| | Page 222 | | Page 224 |
|----|--|----|--|
| 1 | toward biological plausibility, and I felt there | 1 | BY MR. HEGARTY: |
| 2 | was a lot of evidence already for biological | 2 | Q. Yeah. My question is: Are you |
| 3 | plausibility that I didn't need to do an | 3 | aware of either from your own reading or from |
| 4 | exhaustive literature search on the association | | other sources hearing that there are background |
| 5 | between asbestos and ovarian cancer. | | rates of asbestos in certain parts of the United |
| 6 | Q. Do you have an opinion for purposes | | States? |
| 7 | of this case as to the level of exposure to | 7 | A. I have not read that. |
| | asbestos that is necessary to cause ovarian | 8 | Q. Do you have any opinion as to |
| 9 | cancer? | 9 | whether background rates of asbestos just in the |
| 10 | MR. TISI: Objection. | | air are capable of causing ovarian cancer? |
| 11 | THE WITNESS: I think any | 11 | A. I don't have an opinion around that. |
| 12 | exposure to asbestos is important. | 12 | Q. Do you agree that there are exposure |
| 13 | BY MR. HEGARTY: | 13 | levels to asbestos where no harm has been shown? |
| 14 | Q. Is it your opinion that any level of | 14 | A. I'm not aware of that. |
| 15 | exposure to asbestos can cause ovarian cancer? | 15 | And I certainly have not heard any |
| 16 | A. I'm not I didn't do a causal | 16 | regulatory body suggesting that there is a certain |
| 17 | analysis around that, but I would certainly be | | acceptable level of asbestos. |
| 1 | worried about any asbestos contaminant any | 18 | Q. Did you do any analysis in your |
| 1 | asbestos exposure and risk of ovarian cancer. | | report as to the biologic plausibility of asbestos |
| 20 | Q. Do you have an opinion as to the | | fibers causing ovarian cancer? |
| 1 | types of asbestos that have been shown to cause | 21 | A. Could you repeat that, please? |
| 1 | ovarian cancer? | 22 | Q. Sure. |
| 23 | A. No, I don't have an opinion there. | 23 | Did you do any analysis as set out |
| 24 | | l | in your report of the biologic plausibility of |
| | Page 223 | | Page 225 |
| 1 | your voice up. | 1 | asbestos fibers causing ovarian cancer? |
| 2 | THE WITNESS: Sorry. Let me | 2 | A. In my report, I did not dissociate |
| 3 | know if you're not hearing me. | 3 | whether my view on the cause of ovarian cancer is |
| 4 | • | | limited to that exposure which is contaminated |
| 5 | Q. Are you aware of any literature | | with asbestos. |
| | published literature that has stated that asbestos | 6 | Q. Do you have any opinion as to the |
| | in talc applied to the genital area can cause | | exposure levels or dose of asbestos necessary to |
| 1 | ovarian cancer, that the route of delivery of | | be biologically plausible to be a biologically |
| 9 | asbestos via talc can cause ovarian cancer? | 9 | |
| 10 | MR. TISI: Objection. | 10 | MR. TISI: Objection. Let me |
| 11 | THE WITNESS: Yeah. I have | 11 | just put my objection on the record. |
| 12 | not seen those words used, but I have | 12 | Biologically plausible cause |
| 13 | seen many articles where it is | 13 | are inconsistent. |
| 14 | hypothesized that asbestos contamination | 14 | THE WITNESS: Could you |
| 15 | of talc is a biological mechanism by | 15 | please repeat? |
| 16 | which ovarian cancer by which ovarian | l | BY MR. HEGARTY: |
| 17 | cancer could occur. | 17 | Q. Sure. |
| 18 | BY MR. HEGARTY: | 18 | Do you have any opinion as to what |
| 19 | Q. Have you ever read studies or become | | exposure levels or dose of asbestos is necessary |
| 1 | aware of studies reporting that there are | | to have biologic plausibility between ovarian |
| 21 | background rates of asbestos in certain areas of | | cancer and asbestos exposure? |
| | this country? | 22 | MR. TISI: Objection. |
| 23 | MR. TISI: I'm sorry. | 23 | THE WITNESS: Yeah. In my |
| 24 | • | 24 | view, any amount of asbestos |
| | repinase. I mean, repeat it. | 44 | view, any amount of aspesios |

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9

20

contamination is of concern to me. 1

2 BY MR. HEGARTY:

- Do you have any opinion as to the 3
- 4 volume of asbestos that's been -- that has been in
- 5 Johnson's Baby Powder or Shower to Shower over the
- 6 years?
- 7 A. Could you repeat the question again?
- 8 Q.
- 9 Do you have any opinion as to the
- 10 volume of asbestos fibers in Johnson's Baby Powder
- 11 or Shower to Shower over the last 70 years?
- 12 Yeah. Only -- only that over many
- 13 decades asbestiform fibers have been observed in
- 14 the talc products. The volume is -- I don't know
- 15 how -- well, it's -- I have not -- I have no
- 16 opinion about what volume is necessary to make it
- 17 a risk factor. Only that it has consistently been
- 18 shown to be present.
- 19 Do you know what percentage --Q.
- 20 strike that.
- 21 Do you have an opinion as to what
- 22 percentage of Johnson's Baby Powder and Shower to
- 23 Shower bottles manufactured over the years have
- 24 contained any amount of asbestos?

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- 1 I don't have any opinion on what
- 2 proportion of products did and did not have
- 3 contamination. Only that there is evidence to 4 show that many did.
- 5 For purposes of your biologic Q.
- 6 plausibility opinion --7 A. Yes.
- 8 -- is it necessary for a talcum Q.
- 9 powder product to reach the ovaries?
- 10 No. It could cause a carcinogenic
- 11 process in the fallopian tubes. So it doesn't
- 12 necessarily have to have been -- have to have
- 13 reached the ovaries.
- And there's new evidence to suggest 15 that certain epithelial ovarian cancers actually
- 16 arise in the fallopian tubes.
- 17 Can you cite for me any studies that
- 18 have commented on biologic plausibility as it
- 19 relates to talc and ovarian cancer with regard to
- 20 the ovarian -- with regard to the fallopian tubes
- 21 versus the ovaries?
- I have read that some histologic
- 23 subtypes may be more likely to initiate in the
- 24 fallopian tubes as opposed to the ovaries.

1 But I do want to just clarify that

- 2 talc particulates have been observed both in the
- 3 fallopian tubes and in the ovaries.
- 4 My question is a little bit 5 different.
 - Can you cite for me any studies that
- 7 have focused on the fallopian tube with regard to
- 8 talc when discussing biologic plausibility?
 - Only to the extent that -- only to
- 10 the extent that exposure in the fallopian tubes is
- 11 sufficient to, along -- along with -- with actual
- 12 exposure within the ovaries, is sufficient to
- 13 warrant biological plausibility.
- 14 You recall the authors on any of --
- 15 any such study that have talked about that?
- I believe it's possible that 16 A.
- 17 Silkraut might have talked about that.
- You mean Schildkraut? 18 O.
- 19 A. Yeah, Schildkraut.
 - The study we talked about today? Q.
- Yes. Yes. I believe that to be the 21 A.
- 22 case, as I recall.
- 23 With regard to your methodology for Q.
- 24 preparing the report --

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- A. 1 Yes.
- 2 Q. -- at the time you started this
- 3 process, did you and Dr. Rothman share the same
- 4 methodology?
- 5 Yes. I have always used the
- 6 criteria pointed out by Hill as factors to be
- 7 considered but not solely determinant for making a
- 8 causation assessment.
- Can you cite for me any instances
- 10 where you have set out in the published literature
- 11 the methodology you employed in this case for
- 12 analyzing whether talcum powder use can cause
- 13 ovarian cancer?
- 14 Well, I think in my earlier
- 15 publications I followed a similar approach,
- 16 looking at issues related to strength and
- 17 consistency of the association, dose response when
- 18 available, biological plausibility. But always
- 19 taking into consideration biases that could
- 20 explain the findings that we see with respect to
- 21 confounding, misclassification, temporality.
- 22 So -- even recall bias.
- 23 So I would like to think that I have
- 24 taken -- and, frankly, in reading my older

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| | P. 400 | | 5 000 |
|---|---|---|---|
| 1 | Page 230 | 1 | Page 232 |
| | articles, I'm actually quite impressed that I | 2 | MR. TISI: Let me just object to the word "criteria" because that's not |
| | followed those guidelines throughout my career. | 3 | |
| 3 | Q. When you're talking about your | 4 | what it says. THE WITNESS: There I believe |
| 4 | article, are you talking about the articles that | | |
| 5 | you have been author on about talc and ovarian | 5 6 | what we tried to say is that there is no checklist alone that can be used for |
| | cancer? | 7 | |
| 7 | A. Yes. Yes. | | causal inference, and that's the first |
| 8 | Q. Other than those articles, can you | 8 | sentence of the of the next paragraph. "If no checklist for causal |
| | J 1 | 9 | |
| | apply the same methodology as you applied in your | 10 | inference exists, then how does causal |
| | report? | 11 12 | inference proceed?" |
| 12 | A. Oh, virtually all of my articles | | And the way I believe we talk |
| | that relate to the etiology of etiology of a | 13 14 | about it throughout the report is, we |
| | particular adverse outcome. | | look at the components that are indicated |
| 15 | Q. Please look at page 4 of your | 15 16 | as Bradford-Hill components, but always look at them in the context of how they |
| | report. | 17 | could have been influenced by |
| 17 | The section "Overall Approach and Methodology of This Review" sets out your | 18 | bias-related issues, and that's what we |
| | methodology for your analysis of the literature | 19 | tried to to lay out here. So, yeah. |
| | regarding talcum powder use and ovarian cancer, | 20 | BY MR. HEGARTY: |
| | correct? | 21 | Q. So in this part of your report, |
| 22 | A. Yes. | | you're not you're not saying that the |
| 23 | Q. This part of your report refers to | | Bradford-Hill analysis, factors, or criteria, |
| _ | the Bradford-Hill analysis or criteria, but at the | | however you want to characterize it, leads to an |
| | | | |
| | · · · · · · · · · · · · · · · · · · · | | • |
| | Page 231 | | Page 233 |
| 1 | Page 231 end of the first paragraph you write: | 1 | Page 233 unreliable result? |
| 1 2 | Page 231 end of the first paragraph you write: "Unfortunately, despite the fact | 1 2 | Page 233 unreliable result? A. I think if you only do a checklist |
| 1 2 3 | Page 231 end of the first paragraph you write: "Unfortunately, despite the fact that purported lists of causal criteria have been | 1 2 3 | Page 233 unreliable result? A. I think if you only do a checklist without taking into account how that data was |
| 1 2 3 4 | Page 231 end of the first paragraph you write: "Unfortunately, despite the fact that purported lists of causal criteria have been proposed and implemented, a valid set of such | 1 2 3 4 | Page 233 unreliable result? A. I think if you only do a checklist without taking into account how that data was obtained, then, yes, I believe the Bradford |
| 1 2 3 4 5 | Page 231 end of the first paragraph you write: "Unfortunately, despite the fact that purported lists of causal criteria have been proposed and implemented, a valid set of such criteria does not exist." | 1 2 3 4 5 | Page 233 unreliable result? A. I think if you only do a checklist without taking into account how that data was obtained, then, yes, I believe the Bradford criteria do not in and of itself allow for a |
| 1 2 3 4 5 6 | Page 231 end of the first paragraph you write: "Unfortunately, despite the fact that purported lists of causal criteria have been proposed and implemented, a valid set of such criteria does not exist." You see where I'm reading? | 1 2 3 4 5 6 | Page 233 unreliable result? A. I think if you only do a checklist without taking into account how that data was obtained, then, yes, I believe the Bradford criteria do not in and of itself allow for a causal allow for causal inference. |
| 1 2 3 4 5 6 7 | Page 231 end of the first paragraph you write: "Unfortunately, despite the fact that purported lists of causal criteria have been proposed and implemented, a valid set of such criteria does not exist." You see where I'm reading? A. Yes, I do. | 1 2 3 4 5 6 7 | Page 233 unreliable result? A. I think if you only do a checklist without taking into account how that data was obtained, then, yes, I believe the Bradford criteria do not in and of itself allow for a causal allow for causal inference. Q. So as an example, if you only talk |
| 1 2 3 4 5 6 7 8 | Page 231 end of the first paragraph you write: "Unfortunately, despite the fact that purported lists of causal criteria have been proposed and implemented, a valid set of such criteria does not exist." You see where I'm reading? A. Yes, I do. MR. TISI: Let me just object | 1 2 3 4 5 6 7 8 | Page 233 unreliable result? A. I think if you only do a checklist without taking into account how that data was obtained, then, yes, I believe the Bradford criteria do not in and of itself allow for a causal allow for causal inference. Q. So as an example, if you only talk about strength of association there being a |
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I read the ones that I thought were

So I was selective in looking at all

2 most appropriate. So, for example, case series I

4 certain commentaries to see whether or not they

5 were specifically addressing the issue of talc.

7 observational studies and, frankly, there hasn't

8 been any new data collection -- new primary data

9 collection from what I could tell since 2016. So

10 most of the literature that's been published since

In evaluating the studies either

14 from your own search or from what you otherwise

15 had or been provided, did you assess the strengths

Did you assign a weight or a

No. No, I did not. I -- unless --

11 then has been meta-analyses or reanalyses of

3 did not put a lot of stock into. I looked at

Page 236

Page 234

1

6

13

17

18

20

A.

12 existing data.

Q.

A.

Q.

24 scientific validity.

Document 33295-64

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- 1 I can't come up with any other explanation for why
- 2 we see this association for me to then believe
- 3 that the magnitude of the association is
- 4 believable.
- 5 O. In your report, you don't walk
- 6 through and discuss each of the nine Bradford-Hill
- 7 factors or criteria, or however you called it,
- 8 that he set out in his statement, correct?
- 9 A. That's correct.
- For example, you don't talk about 10 Q.
- 11 temporality or experiment. All those other -- all
- 12 the factors, correct?
- 13 A. I -- well, I don't talk about the
- 14 ones that are obviously in place. For example, I
- 15 don't think anybody would believe that ovarian
- 16 cancer leads one to initiate exposure to talc and
- 17 so, therefore, temporality I think seems
- 18 reasonably obvious.
- 19 So we chose to focus on the ones
- 20 that were most contested by colleagues.
- 21 What are the ones that are most
- 22 contested that you focused on?
- 23 Well, certainly the -- the magnitude

1 be occurred -- would occur, the biological

2 plausibility, the consistency of the findings

3 across studies. Those are certainly the ones that

4 we focused on mostly and, in particular, how the 5 assessment of the exposure could have influenced

- 24 of the association, dose response where it could
- - Page 235 1

16 and weaknesses in each paper?

I believe I did.

19 numerical value to the -- to each paper?

21 well, I looked at each paper as its own

22 contribution and what the strengths and

23 limitations were and made a decision on its

- 3 looked at those that were obviously flawed in my
- 4 view versus those that, after an extensive review
- 5 of the data that was available, I felt that the
- 6 all of those factors.
- 7 You mentioned early on in the
- 8 deposition that you did your own literature
- 9 search, correct?
- 10 A. Yes.
- 11 Q. Did anyone assist you in doing that?
- 12 A.
- 13 Q. What literature engines or tools did
- 14 you use?
- 15 A. I used PubMed, Medline.
- Did you prepare in advance a
- 17 protocol for how you were going to research the
- 18 literature?
- 19 No, but I've been researching
- 20 literature for an awful long time. (Laugh). I
- 21 don't think I need a protocol at this point.
- 22 With regard to the materials you
- 23 identified from that literature search, did you
- 24 read them all in their entirety?

- Page 237 I didn't say this one gets ranked as
- 2 a 10; this one gets ranked as a 5. Instead, I

- 6 findings were believable.
- 7 As of the time you started this
- 8 process in preparing your report, had you read all
- 9 of the case-control studies on talc and ovarian
- 10 cancer?
- 11 A. No, I hadn't.
- 12 At the time you started this process Q.
- 13 of preparing your expert report, had you read all
- 14 the cohort studies on talc and ovarian cancer?
- 15 I believe I had read the Gertig one
- 16 in the past, but the one from the Sister Study and
- 17 the one from the WHI I hadn't read.
- 18 Had you read the O'Brien 2020
- 19 meta-analysis or pooled analysis of the four
- 20 cohorts before you were contacted by plaintiffs'
- 21 counsel -- by plaintiffs' counsel about
- 22 participating in this litigation as an expert?
- 23 A. Yes, I did.
 - Q. Had you read all the meta-analyses

60 (Pages 234 - 237)

24

| Page 238 | Page 24 |
|---|--|
| 1 regarding talc and ovarian cancer prior to | 1 Johnson & Johnson has produced as part of this |
| 2 starting this process of preparing your expert | 2 case, have you reviewed any of them? |
| 3 report? | 3 A. I have not that I'm aware of and I'd |
| 4 A. No, I did not. | 4 love to. |
| 5 Q. In particular, had you read | 5 Q. So would it be a fair statement |
| 6 Penninkilampi before you started this process? | 6 that, as of today, you have not done a |
| 7 A. Yeah. No. | 7 comprehensive analysis of the available asbestos |
| 8 Q. Had you read Taher before you | 8 testing documents that have been provided in this |
| | |
| 9 started this process? 10 A. No. | 9 litigation? 10 MR. TISI: Objection. |
| | 3 |
| 11 Q. Had you read Berge before you | 11 Misstates his report. |
| 12 started this process? | 12 THE WITNESS: Yeah, I've |
| 13 A. No, I hadn't. | reviewed. Anything that's been in the |
| 14 Q. As part of your work on this case, | scientific literature I've seen and the |
| 15 have you reviewed any documents, that is internal | Longo report that was provided to me. |
| 16 documents, produced by Johnson & Johnson? | 16 BY MR. HEGARTY: |
| 17 A. No, not that I'm aware of. | 17 Q. But as far as the asbestos testing |
| 18 Q. In particular as to the documents | 18 documents that Johnson & Johnson has produced in |
| 19 produced by Johnson & Johnson, have you reviewed | 19 this case, you have not reviewed? |
| 20 have you reviewed any of the asbestos testing | 20 A. No. |
| 21 documents that Johnson & Johnson has produced in | 21 MR. TISI: Objection. |
| 22 this case? | 22 Let me just |
| 23 A. I I don't recall. I don't I | THE WITNESS: Yeah. |
| 24 don't I don't recall. | MR. TISI: Let me just place |
| Page 239 | Page 24 |
| 1 MR. TISI: Let me just clarify | 1 an objection. |
| 2 this so you know. He was provided with | 2 Misstates his report. |
| 3 the Rothman report which came from the | 3 BY MR. HEGARTY: |
| 4 litigation in this case, which was not | 4 Q. You can answer. |
| 5 published. I just wanted to be clear on | 5 A. To my knowledge, I have not seen |
| 6 that. That was that was a J&J or PCPC | 6 testing that was specifically done by Johnson & |
| 7 report. | 7 Johnson. |
| 8 MR. HEGARTY: I understand. | l |
| | 8 Q. You said you would like to see that. |
| 9 My question | 8 Q. You said you would like to see that. 9 Why would you like to see it? |
| 9 My question 10 THE WITNESS: Oh. | • |
| • • • • • • • • • • • • • • • • • • • | 9 Why would you like to see it? 10 A. Well, I'd like to see the methods |
| 10 THE WITNESS: Oh. 11 MR. HEGARTY: My question is | 9 Why would you like to see it? 10 A. Well, I'd like to see the methods 11 that they used. I'd like to compare them to the |
| 10 THE WITNESS: Oh. 11 MR. HEGARTY: My question is 12 of the laboratory testing results. | 9 Why would you like to see it? 10 A. Well, I'd like to see the methods 11 that they used. I'd like to compare them to the 12 way in which it was done by other by others. |
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| | Page 242 | | Page 244 |
|----|---|----|--|
| | Health Canada, correct? | | has said with regard to talcum powder use and |
| 2 | A. Yes, uh-huh. | | ovarian cancer in your report? |
| 3 | Q. Do you reference anywhere in your | 3 | A. I don't know if it was if I had |
| 4 | report any findings as by FDA as it relates to | | that available at the time of writing the report. |
| 5 | talc and ovarian cancer? | 5 | Q. When you say you had "that," you're |
| 6 | MR. TISI: Objection. | | talking about the FDA denial of the Citizen |
| 7 | Objection. | | Petition letter? |
| 8 | THE WITNESS: I don't believe | 8 | A. Correct. |
| 9 | I let me just think about this. | 9 | Q. Sitting here today, do you know if |
| 10 | Not | | you had it when you prepared your report? |
| 11 | MR. TISI: If you need to look | 11 | A. Honestly, I don't I don't recall, |
| 12 | at your report | | but the problem is, is that was not a scientific |
| 13 | THE WITNESS: Yeah. | 13 | process. It was merely stating certain certain |
| 14 | MR. TISI: feel free to do | | making certain statements that were not |
| 15 | that. | | referenced or was not peer-reviewed or I had no |
| 16 | THE WITNESS: (Reviews | | idea how that response was determined, and all - |
| 17 | document.) | | everything that I have reviewed in here has some |
| 18 | MR. TISI: I mean, do you mind | 18 | scientific basis behind it. |
| 19 | if so I could move it along and help | 19 | So even if I had it, I'm not sure I |
| 20 | you with this? | 20 | would have included it as evidence one way or |
| 21 | MR. HEGARTY: Well, my | 21 | another. Because in the report, in the response, |
| 22 | question | 22 | they say this has not been found, or this has not |
| 23 | MR. TISI: He does cite it in | 23 | been found, or this is the case of something; but |
| 24 | Section B. | 24 | there is no evidence behind those statements. |
| | Page 243 | | Page 245 |
| | BY MR. HEGARTY: | 1 | So I'm not sure it would have met |
| 2 | Q. My question is: Do you do any | 2 | the inclusion criteria for the work the work |
| 3 | analysis, that is, a written analysis in your | _ | that I evaluated. |
| | report yourself of any FDA findings as relates to | | Q. For purposes of your methodology, |
| | talc and ovarian cancer? | | what was the inclusion criteria for you to comment |
| 6 | MR. TISI: Okay. That's a | 6 | on something in your report? |
| 7 | different question. Referring to it as | 7 | A. Scientifically reviewed evidence in |
| 8 | it's referred in Footnote B, but his | 8 | the scientific literature or or the Health |
| 9 | his analysis is a different question than | | Canada report which I included because that had |
| 10 | you asked. | 10 | been peer-reviewed by externally. And things such |
| 11 | THE WITNESS: Yeah. No, I did | 11 | |
| 12 | not. I did not do an analysis, but I did | 12 | MR. HEGARTY: Let's look at a |
| 13 | see the FDA response to a citizens | 13 | couple of things that FDA has said with |
| 14 | committee that was made available to me. | 14 | regard to talc and ovarian cancer, one of |
| 15 | BY MR. HEGARTY: | 15 | which you already mentioned, and I'll |
| 16 | Q. So was it your methodology to refer | 16 | mark that next. |
| 17 | to Health Canada and IARC but not to FDA as it | 17 | But first I wanted to mark as |
| 18 | relates to talc and ovarian cancer? | 18 | Exhibit 15 a printout from FDA's website |
| 19 | MR. TISI: Objection. | 19 | as it relates to talc and ovarian cancer. |
| 20 | Misstates. | 20 | (Document marked for |
| 21 | THE WITNESS: No, it was not | 21 | identification as Harlow Exhibit 15.) |
| 22 | my intent. | 22 | BY MR. HEGARTY: |
| 23 | ¥ | 23 | Q. And, first of all, I'll just ask |
| 24 | Q. Why did you not refer to what FDA | 24 | you: Have you ever looked on FDA's website and |
| | | | |

| | D 24/ | | D 240 |
|---|---|--|--|
| 1 | Page 246 determined what FDA says about talc and ovarian | 1 | Page 248 reviewing scientific literature and why. Now I'll |
| | cancer? | | add to my question. |
| 3 | | 3 | Is that not worth referencing in |
| 4 | | | your report? |
| 5 | • | 5 | A. I have no there's no evidence as |
| 6 | | l | to how are they made that evaluation. So I no |
| 7 | | 7 | My report was based on the |
| 8 | | ' | scientific literature, not what somebody says |
| | Q. Please turn over to the next page of this document. | 9 | |
| 10 | | 10 | Q. You do make reference in your report |
| | 1 2 1 | | · · · · · · · · · · · · · · · · · · · |
| 1 | beginning "Published scientific literature"? | 12 | to review articles, though, correct? |
| 12 | , , | l | A. But those are yes. Well, yes, |
| 13 | | | review articles, but those review articles are |
| 14 | r | l . | peer-reviewed in the scientific literature. |
| 1 | April 3, 2024 says: | 15 | MR. HEGARTY: Let me show |
| 16 | | 16 | you |
| 1 | going back to the 1960s has suggested a possible | 17 | THE WITNESS: Are we done |
| | association between the use of powders containing | 18 | with this? |
| 1 | talc in the genital area and the incidence of | 19 | MR. HEGARTY: We're done with |
| | ovarian cancer. However, these studies have not | 20 | that document. |
| | conclusively demonstrated such a link, or if such | 21 | THE WITNESS: Okay. |
| 1 | a link existed, what risk factors might be | 22 | MR. HEGARTY: Let me show you |
| | involved." | 23 | next the FDA rejection letter of the |
| 24 | Did I read that correctly? | 24 | Citizen Petitions that we talked about |
| | Page 247 | | Page 249 |
| 1 | A TTI411 | | |
| | , 3 | 1 | just a moment ago. |
| 2 | Q. That is a statement that does make | 2 | THE WITNESS: Yeah. |
| 3 | Q. That is a statement that does make reference to FDA reviewing the scientific | 2 3 | THE WITNESS: Yeah. MR. HEGARTY: I marked it as |
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| 1 Number 167 2 Petitions. 3 A. Okay. 4 Q. Do you see that? 5 A. Yes. 6 Q. Those Citizen Petitions were seeking 7 warnings with regard to talcum powder use and 8 ovarian cancer, correct? 9 MR. TISI: Objection. 10 Mischaracterizes. Seeking to make FDA 11 require a warning, which is different. 12 BY MR. HEGARTY: 13 Q. You can answer. 14 A. Welt, this is what it specifically 15 says, for the FDA to require a cancer warning of 16 cosmetic tale products. 17 Q. Looking at the first page of 18 Exhibit 16, the third paragraph, FDA says in this 19 letter: 10 "After careful review" 21 A. This is right here? This paragraph? 22 Q. Yes, right here. 23 A. Got it. 24 Q. "After careful review and 25 the Petitions, and review of additional scientific 4 information, this letter is to advise you that FDA 5 is denying your Petitions. FDA did not find that 6 the data submitted presented conclusive evidence 7 of a causal association between tale use in the 8 perineal area and ovarian cancer." 9 First of all, did I read that 10 correctly? 11 A. That is what it is said. 12 Q. Did you review the Citizen Petitions 13 themselves and see what they provided to FDA? 14 A. I did not. 16 Q. Do you understand, sitting here 17 today, that those are available and you can 18 determine what they provided to FDA? 19 A. I didn't know that they were 20 available. 21 Q. Please turn over next first of 22 A. Have you read the 1993 NTP study had no relevance of the temperature of the except from the 14 the provided to FDA? 18 Exhibit 16, the third paragraph (PDA) 19 A. Uh-hub. 20 Q. Yes, Doctor? 21 A. This is right here? 22 Q. Have you aware oath is letter? 23 A. Got it. 24 Q. Please turn over in Exhibit 16 to 13 page 4. Actually, it starts at page 3 and then 14 carries over to page 4. 15 A. Uh-hub. 26 Q. Do you see on those two pages where 17 FDA is describing the findings of the NTP animal 28 study? 29 Q. Yes, Doctor? 21 A. Thave not. 21 A. Thave not. 22 Q. Have you read the 1993 NTP animal 23 study? 24 A. I have not. 25 Page 25 26 Q. Do you se | | | Page 250 | | | Page 252 |
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| | 1 | | _ | | _ | it in time to for your suggested warning |
| 1.24 your review the letter we're looking at Exhibit 1.24 Does this statement from EDA of | 1 | | | | | |
| 21 your revers the reverse rooming at, Danier 27 Does this statement from FDA of | 24 | your revie | ew the letter we're looking at, Exhibit | 24 | | Does this statement from FDA of |

| | Page 254 | | Page 256 |
|--|---|--|---|
| 1 | their reviewing 15 articles from 1980 to 2008 not | 1 | this section before today? |
| 1 | satisfy your criteria for including a reference to | 2 | A. I have. |
| 1 | this letter in your report? | 3 | Q. This section begins: |
| 4 | A. Well, I don't know. They basically | 4 | "Your third major point is that |
| 5 | said, we reviewed 15 articles that were not cited | 5 | epidemiological studies confirm the causal |
| 6 | in the committee's petition "to determine if there | | relation between genital application of talc and |
| 7 | was additional support at this time to for your | 7 | ovarian cancer, and the protective effect of tubal |
| 1 | suggested" scientific literature studies of acute | 8 | ligation or hysterectomy, preventing the |
| 9 | exposure effects. "FDA did not find enough | 9 | translocation of talc to the ovary." |
| 10 | additional support at this point in time for your | 10 | Did I read that correctly? |
| 11 | suggested warning label." | 11 | A. You did. |
| 12 | I don't know how they made that | 12 | Q. The letter goes on to say: |
| 13 | decision that there was not not enough evidence | 13 | "After consideration of the |
| 14 | to come to this conclusion because I don't know | 14 | scientific literature submitted in support of both |
| 15 | what the 15 articles are, and they're not cited in | 15 | Citizen Petitions" |
| 16 | this report. | 16 | MR. TISI: You know, honestly, |
| 17 | So I would love to be able to look | 17 | you're going really fast. Can you just |
| 18 | at those and to be able to determine whether they | 18 | slow down? Read it. |
| 19 | made a decision that was based on on reliable | 19 | And he's actually in the |
| 20 | and scientifically valid evidence in those 15 | 20 | process of reading while you're asking a |
| 21 | articles. | 21 | question. Read what you want to read and |
| 22 | Q. For purposes of your report, did you | 22 | then allow him to ask the question, but |
| 23 | do a comprehensive review of the toxicity | 23 | don't just speed read to him and ask him |
| 24 | literature with regard to talcum powder exposure? | 24 | if he agrees with it. |
| | | | |
| | Page 255 | | Page 257 |
| 1 | A. I didn't need to do that in order to | | BY MR. HEGARTY: |
| 2 | A. I didn't need to do that in order to be able to assess biological plausibility. | 2 | BY MR. HEGARTY: Q. Doctor, was I reading too fast for |
| 3 | A. I didn't need to do that in order to be able to assess biological plausibility.Q. So you did not do that? | 2 3 | BY MR. HEGARTY: Q. Doctor, was I reading too fast for you? |
| 2 3 4 | A. I didn't need to do that in order tobe able to assess biological plausibility.Q. So you did not do that?A. Correct. | 2 3 4 | BY MR. HEGARTY: Q. Doctor, was I reading too fast for you? A. You can read at whatever speed, and |
| 2 3 4 5 | A. I didn't need to do that in order to be able to assess biological plausibility. Q. So you did not do that? A. Correct. Q. Look under the section "Epidemiology | 2 3 4 5 | BY MR. HEGARTY: Q. Doctor, was I reading too fast for you? A. You can read at whatever speed, and I will take as much time as I need to be able to |
| 2 3 4 5 6 | A. I didn't need to do that in order to be able to assess biological plausibility. Q. So you did not do that? A. Correct. Q. Look under the section "Epidemiology and Etiology Findings." | 2 3 4 5 6 | BY MR. HEGARTY: Q. Doctor, was I reading too fast for you? A. You can read at whatever speed, and I will take as much time as I need to be able to make sure that I digest the information. |
| 2 3 4 5 6 7 | A. I didn't need to do that in order to be able to assess biological plausibility. Q. So you did not do that? A. Correct. Q. Look under the section "Epidemiology and Etiology Findings." MR. TISI: If you need to read | 2 3 4 5 6 7 | BY MR. HEGARTY: Q. Doctor, was I reading too fast for you? A. You can read at whatever speed, and I will take as much time as I need to be able to make sure that I digest the information. MR. TISI: And he's reading. |
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| | B 450 | | 2.00 |
|--|---|--|---|
| 1 | Page 258 MR. TISI: No. | 1 | Page 260 scientifically valid studies did show a dose |
| $\begin{vmatrix} 1 \\ 2 \end{vmatrix}$ | | $\begin{bmatrix} 1 \\ 2 \end{bmatrix}$ | |
| $\frac{2}{3}$ | Are you reading the document, sir? | $\begin{vmatrix} 2 \\ 3 \end{vmatrix}$ | 1 |
| 4 | THE WITNESS: I'm waiting. | 4 | And just if I may? Q. And I'm sorry. |
| 5 | I'm waiting to see what the question is. | 5 | Q. And I'm sorry.A. With respect to lower confidence |
| 6 | MR. TISI: Okay. | _ | intervals of 1.0, that does not mean that the risk |
| 7 | BY MR. HEGARTY: | _ | |
| 8 | Q. Look at paragraph 2 on page 4. FDA | 7 | percent of the time it's going to be somewhere |
| 9 | writes: | 0 | between 1.0 and something greater, and so there is |
| 10 | "Several of the studies acknowledge | | no reason to make the assumption that the |
| 1 | biases in the study design and no single study has | | association is null. |
| | considered all the factors that potentially | 12 | Q. The next paragraph, paragraph 4, |
| 1 | contribute to ovarian cancer, including selection | 1 | says: |
| 1 | bias and/or uncontrolled confounding that result | 14 | "A cogent biologic mechanism |
| 1 | in spurious positive association between talc use | | biological mechanism by which talc might lead to |
| | and ovarian cancer risk." | | · |
| 17 | Did I read that correctly? | 17 | ovarian cancer is lacking." Do you agree that that was an |
| 18 | A. You read that correctly. | 18 | |
| 19 | Q. Do you agree that several studies | 19 | A. No, I do not. |
| 20 | | 20 | Q. Please turn over to the next page, |
| | paragraph? | | page 6. |
| 22 | A. I have no idea of what studies they | 22 | A. Oh, not page 5? |
| | are referring to, so I can't comment on that. If | 23 | Q. I'm sorry. Page 5. Paragraph 6 |
| | they had cited what those studies were, then I | | starts out by referring to the IARC finding. |
| 24 | they had ched what those studies were, then I | 24 | starts out by referring to the TARC finding. |
| 1 | | | |
| 1 | Page 259 | 1 | Page 261 |
| | would be able to comment on it. | 1 2 | A. Yeah. |
| 2 | would be able to comment on it. Q. The next paragraph says: | 2 | A. Yeah.Q. Do you see that? |
| 2 3 | would be able to comment on it. Q. The next paragraph says: "Results of case-control studies do | 2 3 | A. Yeah.Q. Do you see that?A. I do. |
| 2 3 4 | would be able to comment on it. Q. The next paragraph says: "Results of case-control studies do not demonstrate a consistent positive association | 2 3 4 | A. Yeah.Q. Do you see that?A. I do.Q. The letter then goes on to say: |
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| 2 3 4 5 6 | would be able to comment on it. Q. The next paragraph says: "Results of case-control studies do not demonstrate a consistent positive association across studies." Do you agree with that statement? | 2 3 4 5 6 | A. Yeah. Q. Do you see that? A. I do. Q. The letter then goes on to say: "But the results of the Nurses' Health Study, a large prospective cohort study, |
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| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 | would be able to comment on it. Q. The next paragraph says: "Results of case-control studies do not demonstrate a consistent positive association across studies." Do you agree with that statement? A. No, I do not. Q. The next statement says: "Some studies have found small positive associations between talc and ovarian cancer but the lower confidence limits are often close to 1.0." First, do you agree with that part of that sentence? A. That the lower confidence limits are often close to 1.0? Yes. Q. The next part of that paragraph 3 says "and dose-response evidence is lacking." Do you agree that as of 2014, dose-response evidence was lacking? | 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 | A. Yeah. Q. Do you see that? A. I do. Q. The letter then goes on to say: "But the results of the Nurses' Health Study, a large prospective cohort study, revealed no overall association with ever talc use and epithelial ovarian cancer." That's a correct characterization of the Gertig study, correct? A. I think I think it is a selected a selected component from the study that misleads the public as to what the association truly was across different different variations of exposure assessment. Q. With regard to this letter, do you have any experience with FDA response FDA's responses to Citizen Petitions? |
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| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 | would be able to comment on it. Q. The next paragraph says: "Results of case-control studies do not demonstrate a consistent positive association across studies." Do you agree with that statement? A. No, I do not. Q. The next statement says: "Some studies have found small positive associations between talc and ovarian cancer but the lower confidence limits are often close to 1.0." First, do you agree with that part of that sentence? A. That the lower confidence limits are often close to 1.0? Yes. Q. The next part of that paragraph 3 says "and dose-response evidence is lacking." Do you agree that as of 2014, dose-response evidence was lacking? A. No, I do not agree with that. We showed dose response in 1992. | 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 | A. Yeah. Q. Do you see that? A. I do. Q. The letter then goes on to say: "But the results of the Nurses' Health Study, a large prospective cohort study, revealed no overall association with ever talc use and epithelial ovarian cancer." That's a correct characterization of the Gertig study, correct? A. I think I think it is a selected a selected component from the study that misleads the public as to what the association truly was across different different variations of exposure assessment. Q. With regard to this letter, do you have any experience with FDA response FDA's responses to Citizen Petitions? A. No, I have no idea. Q. Have you ever been involved in an FDA review of a Citizen Petition? A. I have not. |
| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 | would be able to comment on it. Q. The next paragraph says: "Results of case-control studies do not demonstrate a consistent positive association across studies." Do you agree with that statement? A. No, I do not. Q. The next statement says: "Some studies have found small positive associations between talc and ovarian cancer but the lower confidence limits are often close to 1.0." First, do you agree with that part of that sentence? A. That the lower confidence limits are often close to 1.0? Yes. Q. The next part of that paragraph 3 says "and dose-response evidence is lacking." Do you agree that as of 2014, dose-response evidence was lacking? A. No, I do not agree with that. | 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 | A. Yeah. Q. Do you see that? A. I do. Q. The letter then goes on to say: "But the results of the Nurses' Health Study, a large prospective cohort study, revealed no overall association with ever talc use and epithelial ovarian cancer." That's a correct characterization of the Gertig study, correct? A. I think I think it is a selected a selected component from the study that misleads the public as to what the association truly was across different different variations of exposure assessment. Q. With regard to this letter, do you have any experience with FDA response FDA's responses to Citizen Petitions? A. No, I have no idea. Q. Have you ever been involved in an FDA review of a Citizen Petition? A. I have not. |

| Page 262 1 Petitions? | Page 264 |
|---|---|
| 2 A. I have not. | 1 know, but they specifically say that "the 2 potential for particulates to migrate |
| 3 Q. This letter was authored by Steve | from the perineum and vagina to the |
| 4 Musser. | 4 peritoneal cavity is indisputable." |
| 5 Do you know Steve Musser? | 5 BY MR. HEGARTY: |
| 6 A. I do not. | 6 Q. What is what does it mean to say |
| 7 Q. Is it your opinion that the doctors | 7 the potential for that to happen is |
| 8 and scientists at FDA involved in responding to | 8 "indisputable"? What's your interpretation of |
| 9 the Citizen Petition were not qualified to assess | 9 that phrase of that terminology? |
| 10 the safety data? | 10 A. That it is plausible |
| 11 A. I can't speak to whether they were | 11 Q. Phraseology. |
| 12 qualified or not. I just believe that what they | 12 A. That it is plausible that the |
| 13 put forward here is is inaccurate. | 13 particulates will migrate. |
| 14 Q. Is it your belief that the that | 14 Q. I'm finished with that document for |
| 15 those involved in putting together this FDA | 15 now, Doctor. |
| 16 response did not do a proper job? | 16 You're familiar with the NIH, |
| 17 A. Yes. | 17 correct? |
| 18 Q. Is it your contention that FDA | 18 A. I am. |
| 19 failed to do its job with regard to the safety of | 19 Q. In fact, your report and your CV |
| 20 talc? | 20 refers to work you've done through the NIH, |
| 21 MR. TISI: Objection. It's | 21 correct? |
| 22 not his medical | 22 A. Yes. |
| 23 THE WITNESS: I can't I | Q. Including you have one grant that |
| 24 can't speak | 24 you're working from from NIH, correct? |
| Page 263 | Page 265 |
| 1 MR. TISI: Objection. Outside | 1 A. I have two. |
| 2 the scope of the report, but you may | 2 Q. You also have another grant pending? |
| 3 answer. | 3 A. No. No. I have a grant that I'm |
| 4 THE WITNESS: I can't speak | 4 the PI of looking at Swedish national registry |
| 5 as to what their responsibility is in | 5 data and its and factors that influence |
| 6 this situation. | 6 unexplained vulvar pain, and I'm the PI of a |
| 7 BY MR. HEGARTY: | 7 subcontract with the Prevention of Lower Urinary |
| 8 Q. Is it your contention that FDA | 8 Tract Symptoms Research Consortium on women's |
| 9 believes that there is a risk of ovarian cancer | 9 urological health. Those are both NIH grants. |
| 10 with talc use and has chosen to do nothing about | |
| 11 it? | 11 committees, correct? |
| 12 A. I | 12 A. I have. |
| 13 MR. TISI: Objection. Calls | 13 Q. You agree with me that the NIH is |
| 14 for speculation. | 14 the federal government's primary health agency on |
| 15 THE WITNESS: Yeah. Again, I | 15 cancer research in the U.S., correct? |
| 16 cannot speculate on that.17 BY MR. HEGARTY: | 16 A. That's correct. |
| | 17 Q. Do you agree that the NCI is a |
| 18 Q. Is it your opinion or your belief | 18 capable and reliable resource in this country for 19 information on cancer? |
| 19 that FDA believes there is a warning that's20 necessary on talcum powder products for ovariar | |
| 21 cancer, but they're just not going to require it? | ū |
| 22 MR. TISI: Objection. Calls | 21 THE WITNESS: Yeah. I think 22 the I can't speak to their decisions |
| 23 for speculation. | on what to have as outward-facing to the |
| 24 THE WITNESS: Yeah. I don't | 24 public. |
| | Δ¬ puone. |

| Page 266 | Page 268 |
|---|--|
| 1 BY MR. HEGARTY: | 1 Q. Sure. |
| 2 Q. Do you agree that NCI is a reliable | 2 Is it your contention that documents |
| 3 resource for doctors with regard to cancer | 3 put out by NCI with regard to cancer are not |
| 4 research? | 4 necessarily reliable and can be relied upon by |
| 5 MR. TISI: Objection. | 5 doctors who are treating patients for cancer? |
| 6 Objection. Vague. | 6 A. I can't say that that's the case |
| 7 THE WITNESS: I think no. | 7 across the board. I think it depends on what |
| 8 MR. TISI: Depending upon the | 8 what they are putting out and whether what they're |
| 9 issue. Go ahead. | 9 putting out is is indisputable or is accurate |
| 10 THE WITNESS: Yeah. No, I | 10 in terms of representing the view of the |
| 11 think a reliable resource for for | 11 scientific community. |
| doctors and everyone should be evidence | 12 Q. Starting on page 16 of your report, |
| from the scientific literature. If it is | 13 you make reference to the NCI's Physician Data |
| 14 accurately evaluated, then it can be a | 14 Query, or PDQ, correct? |
| resource in the external-facing website | 15 A. That's correct. |
| 16 of the NCI. | 16 Hold on. Let me just. I'll pull |
| 17 BY MR. HEGARTY: | 17 that up. |
| 18 Q. You have served on NCI committees, | 18 Q. And I'll |
| 19 correct? | 19 A. Oh, in my report. |
| 20 A. I served on the Board of Scientific | 20 Q. I'm going to mark it as an exhibit. |
| 21 Counselors. No. Board board of I think | 21 A. Okay. |
| 22 it's the Board of Scientific Counselors for the | 22 Q. My reference was simply to |
| 23 NCI which evaluates intramural research, which is | 23 A. Okay. |
| 24 research that is done by investigators at NCI that | 24 Q page 16 of your report. |
| | |
| Page 267 1 work out of NCI itself. | Page 269 1 A. Yeah. Yeah. |
| 2 Q. Was the work you did and reported | 2 Q. Prior to being contacted by |
| 3 out of that committee reliable? | 3 plaintiffs' counsel about serving as an expert |
| 4 MR. TISI: Objection. | 4 witness in this litigation, had you ever read an |
| 5 THE WITNESS: Well, that | 5 NCI PDQ on ovarian cancer? |
| 6 that committee evaluates the scientific | 6 A. I had not. |
| 7 approach and scientific rigor of research | 7 Q. Since being contacted by plaintiffs' |
| 8 that is being done by NCI internal | 8 counsel about serving as an expert witness in this |
| 9 investigators, and they publish their | 9 case, have you reviewed all the NCI PDQs on |
| research in the scientific literature, | 10 ovarian cancer that NCI has put out over the |
| just like those of us who are outside of | 11 years? |
| the NCI and any other government | 12 A. I have reviewed many of them. |
| 13 organization. | 13 Q. With regard to those you reviewed, |
| 14 BY MR. HEGARTY: | 14 did you get them from counsel for plaintiffs? |
| 15 Q. So is it your testimony that | 15 A. I I went some I got from the |
| 16 anything NCI puts out with regard to cancer is not | 16 counsel and some I went onto the PDQ site myself |
| 17 necessarily a reliable authority that doctors can | 17 and pulled off. |
| 18 rely on? | 18 Q. Your report on page 17 refers to the |
| 19 MR. TISI: Objection. | 19 2023 NCI PDQ? |
| 20 THE WITNESS: Yeah. | 20 A. That's correct. |
| 21 MR. TISI: Form. | 21 Q. When did you first review the NCI |
| 22 THE WITNESS: Could you | 22 PDQ you refer to on page 17 of your report? |
| 23 repeat that question? | 23 A. Yeah, in the process of preparing |
| | 24 the report. |
| 24 BY MR. HEGARTY: | 74 HIG GDOH |

| | Page 270 | | Page 272 |
|--|--|--|---|
| 1 | MR. HEGARTY: I'm going to | 1 | A. No, I don't I don't dispute that |
| 2 | mark as the next exhibit, which is | | that's what they are intending to do. |
| 3 | Exhibit 17, the current version of the | 3 | Q. Looking at the well, let me |
| 4 | NCI PDQ that is on NCI's website. | | before I go there. |
| | - | 5 | |
| 5 | (Document marked for | | You said that that's not you |
| 6 | identification as Harlow Exhibit 17.) | | don't dispute that that's what they intended to |
| 7 | THE WITNESS: Is this 2023? | | do. |
| 8 | BY MR. HEGARTY: | 8 | You've read this document, correct? |
| 9 | Q. If you look over on page 25 of 27, | 9 | A. Uh-huh. |
| | at the top, do you see where this refers to the | 10 | Q. Yes? |
| | latest update as being from March 6, 2024? | 11 | A. Yes. |
| 12 | A. Yeah. Ah. Yes. Yes, yes, yes. | 12 | Q. Did the NCI PDQ board that put this |
| 13 | Q. Have you have you reviewed the | | out provide "an information summary for health |
| 14 | March 6, 2024 NCI | | professionals that provides comprehensive, |
| 15 | A. I have. | 15 | peer-reviewed, evidence-based information about |
| 16 | Q PDQ? | 16 | ovarian, fallopian tube, and primary peritoneal |
| 17 | A. I have. | 17 | cancers prevention"? |
| 18 | Q. When did you review it | 18 | MR. TISI: Objection. Asked |
| 19 | A. Recently. | 19 | and answered. |
| 20 | Q first time? | 20 | THE WITNESS: It is what they |
| 21 | A. Recently, but it was not available | 21 | intended to do, and that's that's the |
| 22 | in my report. | 22 | answer. |
| 23 | Q. Please turn over to page 25 of 27. | 23 | BY MR. HEGARTY: |
| 24 | A. That's where we were before, right? | 24 | Q. Do you agree that they did do that, |
| | Page 271 | | Page 273 |
| 1 | Q. That's right. | 1 | not that they intended to do it? |
| 2 | A. "About This PDQ Summary"? | 2 | A. No, I agree that they did it. |
| 3 | Q. Yes. Under the section "Purpose of | 3 | Q. Okay. Under the section "Reviewers |
| | This Summary." | 4 | and Updates," do you see where |
| 5 | Do you see where I'm pointing to? | 5 | A. Where is that? |
| 6 | A. Yes, uh-huh. | 6 | Q. It's in the same page just below |
| 7 | Q. It states that: | | where we were reading. |
| 8 | "This PDQ cancer information summary | | A. Same page? |
| | for health professionals provides comprehensive | | Q. Still page 25 of 27. |
| , | | | A. Oh. I'm sorry. 25 of 27. No, I |
| 10 | | | |
| | peer-reviewed, evidence-based information about | | • |
| 11 | ovarian fallopian tube, and primary peritoneal | 11 | was oh, okay. I'm sorry. Where on 25 again? |
| 11 12 | ovarian fallopian tube, and primary peritoneal cancers prevention." | 11 12 | was oh, okay. I'm sorry. Where on 25 again? Q. Under the section "Reviewers and |
| 11 12 13 | ovarian fallopian tube, and primary peritoneal cancers prevention." Do you dispute that that's what this | 11 12 13 | was oh, okay. I'm sorry. Where on 25 again? Q. Under the section "Reviewers and Updates." |
| 11 12 13 14 | ovarian fallopian tube, and primary peritoneal cancers prevention." Do you dispute that that's what this NCI PDQ does? | 11 12 13 14 | was oh, okay. I'm sorry. Where on 25 again? Q. Under the section "Reviewers and Updates." MR. TISI: Right here. |
| 11 12 13 14 15 | ovarian fallopian tube, and primary peritoneal cancers prevention." Do you dispute that that's what this NCI PDQ does? A. That's what they indicate it does. | 11 12 13 14 15 | was oh, okay. I'm sorry. Where on 25 again? Q. Under the section "Reviewers and Updates." MR. TISI: Right here. THE WITNESS: Got it. |
| 11 12 13 14 15 16 | ovarian fallopian tube, and primary peritoneal cancers prevention." Do you dispute that that's what this NCI PDQ does? A. That's what they indicate it does. Q. My question, though, is: Do you | 11 12 13 14 15 16 | was oh, okay. I'm sorry. Where on 25 again? Q. Under the section "Reviewers and Updates." MR. TISI: Right here. THE WITNESS: Got it. BY MR. HEGARTY: |
| 11 12 13 14 15 16 17 | ovarian fallopian tube, and primary peritoneal cancers prevention." Do you dispute that that's what this NCI PDQ does? A. That's what they indicate it does. Q. My question, though, is: Do you dispute that that's what this NCI PDQ does? | 11 12 13 14 15 16 17 | was oh, okay. I'm sorry. Where on 25 again? Q. Under the section "Reviewers and Updates." MR. TISI: Right here. THE WITNESS: Got it. BY MR. HEGARTY: Q. The second paragraph says: |
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| 11 12 13 14 15 16 17 18 19 | ovarian fallopian tube, and primary peritoneal cancers prevention." Do you dispute that that's what this NCI PDQ does? A. That's what they indicate it does. Q. My question, though, is: Do you dispute that that's what this NCI PDQ does? MR. TISI: Objection. Asked and answered. | 11 12 13 14 15 16 17 18 | was oh, okay. I'm sorry. Where on 25 again? Q. Under the section "Reviewers and Updates." MR. TISI: Right here. THE WITNESS: Got it. BY MR. HEGARTY: Q. The second paragraph says: "Board members review recently published articles each month to determine whether |
| 11 12 13 14 15 16 17 18 19 20 | ovarian fallopian tube, and primary peritoneal cancers prevention." Do you dispute that that's what this NCI PDQ does? A. That's what they indicate it does. Q. My question, though, is: Do you dispute that that's what this NCI PDQ does? MR. TISI: Objection. Asked and answered. THE WITNESS: That's what | 11 12 13 14 15 16 17 18 | was oh, okay. I'm sorry. Where on 25 again? Q. Under the section "Reviewers and Updates." MR. TISI: Right here. THE WITNESS: Got it. BY MR. HEGARTY: Q. The second paragraph says: "Board members review recently |
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| 11 12 13 14 15 16 17 18 19 20 21 | ovarian fallopian tube, and primary peritoneal cancers prevention." Do you dispute that that's what this NCI PDQ does? A. That's what they indicate it does. Q. My question, though, is: Do you dispute that that's what this NCI PDQ does? MR. TISI: Objection. Asked and answered. THE WITNESS: That's what they specifically say it does. | 11 12 13 14 15 16 17 18 19 20 21 | was oh, okay. I'm sorry. Where on 25 again? Q. Under the section "Reviewers and Updates." MR. TISI: Right here. THE WITNESS: Got it. BY MR. HEGARTY: Q. The second paragraph says: "Board members review recently published articles each month to determine whether an article should: be discussed at a meeting, be cited with text, or" turn the page. |

| 1 | Page 274 | Page 276 |
|--|---|---|
| 1 | Did I read that correctly? | 1 answer the question you just gave him? |
| 2 | MR. TISI: He just read the | 2 (Document marked for |
| 3 | second paragraph. Please read the whole | 3 identification as Harlow Exhibit 18.) |
| 4 | thing, sir. | 4 MR. TISI: Go ahead. Next |
| 5 | MR. HEGARTY: Chris, can you | 5 one. |
| 6 | wait until you ask your questions? | 6 BY MR. HEGARTY: |
| 7 | MR. TISI: No. Honestly, | 7 Q. I marked this document as |
| 8 | you | 8 Exhibit 19. |
| 9 | MR. HEGARTY: That rule does | 9 A. I believe it says 18. |
| 10 | not apply at depositions. | 10 Q. I'm sorry. Thank you for correcting |
| 11 | MR. TISI: All right. | 11 me. Exhibit 18. I don't want to mess up the |
| 12 | MR. HEGARTY: You know that. | 12 exhibits. |
| 13 | MR. TISI: You know, you | 13 A. Uh-huh. |
| 14 | know you know what you are doing. You | |
| 15 | are cherry-picking. You are | 15 Screening and Prevention Editorial Board Members |
| 16 | cherry-picking sentences out of context, | 16 Report right now? |
| 17 | and I want him to have the opportunity to | 17 A. I have, actually. |
| 18 | read the documents that you put in front | 18 Q. Do you know any of the board |
| 19 | of him. | 19 members? |
| 20 | MR. HEGARTY: You will have | 20 A. I do not. |
| 21 | your turn at the end of my examination to | 21 Q. There is a board member from |
| 22 | ask him that. | 22 University of Washington. |
| 23 | MR. TISI: I understand, but, | 23 Do you know her? |
| 24 | you know, honestly, it's unfair to ask a | 24 A. I don't. |
| | Page 275 | |
| | 1 age 275 | |
| 1 | witness without giving the opportunity to | Page 277 1 O. There's also a board member from |
| $\begin{vmatrix} 1 \\ 2 \end{vmatrix}$ | witness without giving the opportunity to read. You're not asking him: Do you | 1 Q. There's also a board member from |
| 2 | read. You're not asking him: Do you | Q. There's also a board member from Harvard Medical School, Lydia Pace. |
| 2 3 | read. You're not asking him: Do you need to read this? Do you need to read | Q. There's also a board member from Harvard Medical School, Lydia Pace. Do you know her? |
| 2 3 4 | read. You're not asking him: Do you need to read this? Do you need to read the entire sentence? | Q. There's also a board member from Harvard Medical School, Lydia Pace. Do you know her? A. I don't. |
| 2 3 4 5 | read. You're not asking him: Do you need to read this? Do you need to read the entire sentence? You're just reading sentences | Q. There's also a board member from Harvard Medical School, Lydia Pace. Do you know her? A. I don't. Q. Do you contend that the members of |
| 2 3 4 5 6 | read. You're not asking him: Do you need to read this? Do you need to read the entire sentence? You're just reading sentences and ask him: Did I read this correctly? | Q. There's also a board member from Harvard Medical School, Lydia Pace. Do you know her? A. I don't. Q. Do you contend that the members of the NCI PDQ board that are responsible for the NCI |
| 2 3 4 5 6 7 | read. You're not asking him: Do you need to read this? Do you need to read the entire sentence? You're just reading sentences and ask him: Did I read this correctly? MR. HEGARTY: Please limit | Q. There's also a board member from Harvard Medical School, Lydia Pace. Do you know her? A. I don't. Q. Do you contend that the members of the NCI PDQ board that are responsible for the NCI PDQ on ovarian cancer are not experts in their |
| 2 3 4 5 6 | read. You're not asking him: Do you need to read this? Do you need to read the entire sentence? You're just reading sentences and ask him: Did I read this correctly? MR. HEGARTY: Please limit your objections | Q. There's also a board member from Harvard Medical School, Lydia Pace. Do you know her? A. I don't. Q. Do you contend that the members of the NCI PDQ board that are responsible for the NCI PDQ on ovarian cancer are not experts in their fields? |
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| 2 3 4 5 6 7 8 9 | read. You're not asking him: Do you need to read this? Do you need to read the entire sentence? You're just reading sentences and ask him: Did I read this correctly? MR. HEGARTY: Please limit your objections MR. TISI: No, I'm not going | Q. There's also a board member from Harvard Medical School, Lydia Pace. Do you know her? A. I don't. Q. Do you contend that the members of the NCI PDQ board that are responsible for the NCI PDQ on ovarian cancer are not experts in their fields? MR. TISI: Objection. |
| 2 3 4 5 6 7 8 9 | read. You're not asking him: Do you need to read this? Do you need to read the entire sentence? You're just reading sentences and ask him: Did I read this correctly? MR. HEGARTY: Please limit your objections MR. TISI: No, I'm not going to. MR. HEGARTY: to what the | 1 Q. There's also a board member from 2 Harvard Medical School, Lydia Pace. 3 Do you know her? 4 A. I don't. 5 Q. Do you contend that the members of 6 the NCI PDQ board that are responsible for the NCI 7 PDQ on ovarian cancer are not experts in their 8 fields? 9 MR. TISI: Objection. 10 THE WITNESS: I don't know 11 what their fields are. I don't know |
| 2 3 4 5 6 7 8 9 10 | read. You're not asking him: Do you need to read this? Do you need to read the entire sentence? You're just reading sentences and ask him: Did I read this correctly? MR. HEGARTY: Please limit your objections MR. TISI: No, I'm not going to. MR. HEGARTY: to what the court has asked us all to do, which is to | 1 Q. There's also a board member from 2 Harvard Medical School, Lydia Pace. 3 Do you know her? 4 A. I don't. 5 Q. Do you contend that the members of 6 the NCI PDQ board that are responsible for the NCI 7 PDQ on ovarian cancer are not experts in their 8 fields? 9 MR. TISI: Objection. 10 THE WITNESS: I don't know 11 what their fields are. I don't know 12 whether they are experts on evaluating |
| 2 3 4 5 6 7 8 9 10 11 12 13 | read. You're not asking him: Do you need to read this? Do you need to read the entire sentence? You're just reading sentences and ask him: Did I read this correctly? MR. HEGARTY: Please limit your objections MR. TISI: No, I'm not going to. MR. HEGARTY: to what the court has asked us all to do, which is to form of the question. | 1 Q. There's also a board member from 2 Harvard Medical School, Lydia Pace. 3 Do you know her? 4 A. I don't. 5 Q. Do you contend that the members of 6 the NCI PDQ board that are responsible for the NCI 7 PDQ on ovarian cancer are not experts in their 8 fields? 9 MR. TISI: Objection. 10 THE WITNESS: I don't know 11 what their fields are. I don't know 12 whether they are experts on evaluating |
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| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 | read. You're not asking him: Do you need to read this? Do you need to read the entire sentence? You're just reading sentences and ask him: Did I read this correctly? MR. HEGARTY: Please limit your objections MR. TISI: No, I'm not going to. MR. HEGARTY: to what the court has asked us all to do, which is to form of the question. MR. TISI: I have been doing. I have almost made no objections. I do object to you taking documents, reading sentences out of context and ask if you read them correctly. Objection to form. MR. HEGARTY: Doctor, I'm | 1 Q. There's also a board member from 2 Harvard Medical School, Lydia Pace. 3 Do you know her? 4 A. I don't. 5 Q. Do you contend that the members of 6 the NCI PDQ board that are responsible for the NCI 7 PDQ on ovarian cancer are not experts in their 8 fields? 9 MR. TISI: Objection. 10 THE WITNESS: I don't know 11 what their fields are. I don't know 12 whether they are experts on evaluating 13 talc and ovarian cancer risk. 14 BY MR. HEGARTY: 15 Q. Do you contend that the members of 16 the NCI PDQ Board that we're looking at in 17 Exhibit 18 did not review the pertinent literature 18 on talcum powder and ovarian cancer in preparing 19 Exhibit Number 17? 20 A. No, I don't dispute that they didn't |
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| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 | read. You're not asking him: Do you need to read this? Do you need to read the entire sentence? You're just reading sentences and ask him: Did I read this correctly? MR. HEGARTY: Please limit your objections MR. TISI: No, I'm not going to. MR. HEGARTY: to what the court has asked us all to do, which is to form of the question. MR. TISI: I have been doing. I have almost made no objections. I do object to you taking documents, reading sentences out of context and ask if you read them correctly. Objection to form. MR. HEGARTY: Doctor, I'm going to mark next as Exhibit 18 the PDQ Screening and Prevention Editorial Board. | 1 Q. There's also a board member from 2 Harvard Medical School, Lydia Pace. 3 Do you know her? 4 A. I don't. 5 Q. Do you contend that the members of 6 the NCI PDQ board that are responsible for the NCI 7 PDQ on ovarian cancer are not experts in their 8 fields? 9 MR. TISI: Objection. 10 THE WITNESS: I don't know 11 what their fields are. I don't know 12 whether they are experts on evaluating 13 talc and ovarian cancer risk. 14 BY MR. HEGARTY: 15 Q. Do you contend that the members of 16 the NCI PDQ Board that we're looking at in 17 Exhibit 18 did not review the pertinent literature 18 on talcum powder and ovarian cancer in preparing 19 Exhibit Number 17? 20 A. No, I don't dispute that they didn't 21 review the literature. |

| D 270 | P. 200 |
|---|---|
| Page 278 1 A. I would assume that they do. | Page 280 1 fact that meta-analyses did not show any kind of a |
| 2 Q. Do you contend that the statements | 2 dose-response relationship, but the overall |
| 3 that they make in the NCI PDQ on ovarian cancer | 3 association cited I agree with. |
| 4 and talc are false? | 4 Oh, and also in their citation of |
| 5 MR. TISI: Take a look at it | 5 the of the pooled analysis from the Ovarian |
| 6 before. | 6 Cancer Association Consortium, I agree with their |
| 7 THE WITNESS: What particular | 7 citation of what the overall association. But |
| 8 statements are we referring to? | 8 their their their contention that lifetime |
| 9 BY MR. HEGARTY: | 9 numbers of applications was not was not |
| 10 Q. In Exhibit 17, the statements on | 10 statistically significant, making an assumption |
| 11 talc and ovarian cancer over on page 21 of 27 | 11 that there was no increase in risk with increasing |
| 12 carrying over to page 22 of 27. | 12 numbers of exposure, was simply based on |
| 13 A. Right. There we go. | 13 statistical significance. |
| 14 Q. First of all, before I ask, I'll go | Whereas, as I recall when going back |
| 15 back to that question. | 15 and looking at that, and you look at the lower and |
| You have read before today the | 16 upper 95 percent confidence bounds, you see a |
| 17 section on "Perineal Talc Exposure" on pages 21 | 17 shifting of increased risk over increasing |
| 18 and 22? | 18 exposure. |
| 19 A. Yes. | 19 So the way in which they |
| Q. You're familiar with what that says, | 20 characterize that I felt was not accurate. |
| 21 correct? | 21 They cite they cite that the |
| 22 A. I am. | 22 subset analysis of the prospective study I |
| 23 Q. Going back to my question: Do you | 23 believe that was by Woolen; is that correct? Is |
| 24 contend that the statements in the section on | 24 that the citation? |
| Page 279 | Page 281 |
| 1 "Perineal Talc Exposure" are false? | 1 Q. Yes. |
| 2 MR. TISI: Objection. Take a | 2 A. Yeah. They they said |
| 3 look if you need to. | 3 yeah, they yeah, they they were let's |
| 4 THE WITNESS: (Reviews | 4 see. |
| 5 document.) | 5 The subset analysis of the |
| 6 There are some statements here | 6 prospective study was essentially made by the |
| 7 that I believe are false. | 7 original report. |
| 8 BY MR. HEGARTY: | 8 Right. First of all, I think they |
| 9 Q. Which statements do you believe are | 9 made an incorrect they made an incorrect |
| 10 false? | 10 citation in this. |
| 11 A. The first sentence. | But in any case, I believe that they |
| 12 Q. Any other statements? 13 A. "Results from case" | 12 were stating something about the approach of |
| | 13 excluding two of the three cohort studies was sort |
| Q. I'm sorry. Go ahead. A. "Results from case-control and" | 14 of cherry-picking, and I believe that it was not, |
| | 15 and that the other two cohort studies are are |
| 16 cohort studies are inconsistent, so the data are | 16 very much flawed in terms of selection bias and |
| 17 inadequate to support an association between | 17 exposure assessment. |
| 18 perineal talc exposure and an increased risk of 19 ovarian cancer." | 18 (Reviews document.) |
| | 19 Again, I feel that the first |
| Q. What other statements do you contend 21 in that section are false? | |
| | 21 only discuss the overall association of 1.09 and |
| A. Hang on a second. Right. | 22 not the fact that there was stronger associations 23 observed when more appropriately assessing the |
| 1 19KH 10011A WITH THA NAVE CANTANAA | |
| I take issue with the next sentence that cited the study by Huncharek as as the | 24 exposure that was was left out. |

| Page 282 | Page 284 |
|---|--|
| 1 And I think any reference to the | 1 incorrect? |
| 2 Women's Health Initiative is flawed because they | 2 A. Hold on a second. I might have made |
| 3 didn't start recruiting women until after the age | 3 a mistake, which can happen. |
| 4 of 50, when many women who would have already been | 4 (Reviews document.) |
| 5 diagnosed with ovarian cancer could not have been | 5 "Was inconsistent with the main |
| 6 included, and so I find that to be a poor example | 6 findings." The meaning of the statement is |
| 7 of a cohort study to be used to assess this | 7 unclear. The PDQ goes on to cite the Gertig |
| 8 association. | 8 analysis. |
| 9 I think that's plenty. | 9 That might have been an error in the |
| 10 Q. You make the statement in your | 10 citation there. |
| 11 expert report at page 17 | 11 Q. You've read the Woolen paper, |
| 12 A. Yes. | 12 correct? |
| 13 Q that the that with regard to | 13 A. I have. |
| 14 the comment on the Woolen study that they | 14 Q. And you saw where they used a subse |
| | 15 of data from the Nurses' Health Study 1, correct |
| 15 "incorrectly cited in the PDQ report as O'Brien et 16 al." | 16 A. Yes. |
| | 17 Q. That subset of data was unpublished |
| Do you see where I'm referring you | 18 data, correct? |
| 18 to? | |
| 19 A. Yes, I do. | , , , , |
| Q. What do you mean when you say | 20 the Nurses' Health Study. That's my that's my |
| 21 "incorrectly cited in the PDQ report as O'Brien et | 21 understanding. |
| 22 al."? | MR. HEGARTY: I'll mark so you |
| A. I believe they they made an error | can look at it |
| 24 in which study they were citing. So. | 24 THE WITNESS: Yeah. |
| Page 283 | Page 285 |
| 1 Q. Why do you believe they made an | 1 MR. HEGARTY: as Exhibit |
| 2 error? | Number 19 the Woolen paper. |
| A. Because I thought that they cited | 3 (Document marked for |
| 4 the wrong they made the wrong citation. | 4 identification as Harlow Exhibit 19.) |
| 5 So what's inconsistent with the | 5 THE WITNESS: Yeah. |
| 6 meaning of this statement is unclear, but the PDQ | 6 BY MR. HEGARTY: |
| 7 goes on to cite the Gertig analysis. | 7 Q. This is a paper you've read, |
| 8 So in let's see. When they talk | 8 correct? |
| 9 about the Gertig analysis, which is the 1.09, | 9 A. Yes. |
| 10 reference 13 no, that wasn't it. There was | 10 Q. If you look over on the second page, |
| 11 another location I thought. | 11 in the upper right-hand corner, it describes that |
| 12 Q. And the reason I ask you | 12 the it describes the data that they got from |
| 13 A. Yeah. | 13 the Nurses' Health Study, correct? |
| 14 Q is because at the end of that | In particular, if you look at the |
| 15 sentence that you're referring to, it says: | 15 very last couple of sentences, it says: |
| 16 "The subset analysis" that same. | 16 "The data from NHS 1" |
| 17 A. Oh. | MS. PARFITT: Mark, I'm sorry. |
| 18 Q. "The subset analysis of the | 18 Where are you? |
| 19 prospective study was inconsistent with the main | 19 MR. HEGARTY: I'm on page |
| 20 findings of the original report" refers to the | 20 THE WITNESS: 2527. |
| 21 O'Brien study, correct? | 21 MR. HEGARTY: 2527 in the |
| 22 A. Yeah. | 22 upper right-hand corner. |
| | |
| 23 O. So do you still say that their | MS. PARFILL: Thank vou. |
| Q. So do you still say that theirreference at the end of that sentence was | 23 MS. PARFITT: Thank you. 24 BY MR. HEGARTY: |

| 1 | Page 286 | 1 | Page 288 |
|----|--|----|--|
| 1 | Q. It says: | 1 | me exactly where that is. |
| 2 | "The data from NHS 1 were provided | | BY MR. HEGARTY: |
| | and described in the Supplemental Table 1 and are | 3 | Q. Sure. I'm looking now back at the |
| | included in the systematic review. The data from | | NCI PDQ. |
| | the SIS study were not provided to us due to the | 5 | A. Okay. Let me just go back to the |
| | small sample size of exposed individuals in the | 6 | |
| | highest exposure category." | 7 | Q. Back to the section that you called |
| 8 | What that section is saying is that | 8 | , 1 |
| 9 | they got the data from the NHS 1 study, correct? | 9 | A. Yes. |
| 10 | A. That's correct. | 10 | Q. And do you see where in the NCI PDQ |
| 11 | Q. And do you understand that that was | | it says: |
| 1 | unpublished data? | 12 | "The subset analysis of the |
| 13 | A. I don't know whether it was | | prospective study" that's the NHS study "was |
| | unpublished. They just got the actual data | | inconsistent with the main findings of the |
| 1 | itself. It may have been part of the Gertig | | original report" citing to O'Brien. |
| 1 | analysis. | 16 | So what they're saying there is that |
| 17 | Q. Please look over to page 2569 I'm | | the subset analysis in Woolen was inconsistent |
| | sorry 2529. | | with the overall reported findings from O'Brien, |
| 19 | At the very bottom where the | | correct? |
| | footnote is referring to, that is Footnote 5 | 20 | MR. TISI: Objection. |
| 1 | referring to O'Brien? | 21 | THE WITNESS: (Reviews |
| 22 | A. Yes. | 22 | document.) |
| 23 | Q. The NHS data. | 23 | Yes, it appears that they |
| 24 | Do you see where it says: | 24 | that they have additional they had |
| | Page 287 | | Page 289 |
| 1 | "O'Brien did not publish on daily | 1 | additional information that was not part |
| 2 | exposure for the National Health Study | 2 | of it. That's correct. |
| 3 | participants. However, these data were available | 3 | |
| 4 | and O'Brien provided these data for inclusion"? | 4 | Q. So what they say or what they cite |
| 5 | A. Yes, I see that. | 5 | j j |
| 6 | Q. Is that telling you that the data | | report is accurate, correct? |
| 1 | that's reported as to as to Study 11 in the | 7 | MS. PARFITT: Objection. |
| | table above was unpublished data? | 8 | Sorry. |
| 9 | A. (Reviews document.) | 9 | MR. TISI: Objection. |
| 10 | 3 | 10 | THE WITNESS: Yeah, I may have |
| | know. | 11 | I may have misinterpreted that. |
| 12 | Q. And going back to your report, what | 12 | I was when I was looking at |
| | NCI is saying in this PDQ is that the findings in | 13 | this, my concern was that people felt |
| 1 | Woolen, which represent a subset analysis, was | 14 | that the exclusion of the sisters health |
| 1 | inconsistent with the main findings of the | 15 | study the Sister Study and the Women's |
| | original report, and they refer to O'Brien. | 16 | Health Initiative were a concern on the |
| 17 | So what they're saying there is that | 17 | part of the PDQ, and my belief was that |
| 1 | the Woolen findings were inconsistent with the | 18 | it was an appropriate exclusion from |
| 1 | overall findings of what O'Brien reported in their | | their analyses. |
| 20 | • | | BY MR. HEGARTY: |
| 21 | Do you see that? | 21 | Q. Ultimately, in the NCI PDQ, the |
| 22 | MR. TISI: Objection. | | document itself says that: |
| 23 | Misstates. | 23 | "Results from case-control and |
| 24 | THE WITNESS: So show show | 24 | cohort studies are inconsistent, so the data are |

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| 1 | Page 290 | 1 | Page 292 |
|--|---|--|--|
| 1 | inadequate to support an association between | | doctors reading this NCI PDQ should not rely on it |
| | perineal talc exposure and an increased risk of ovarian cancer." | 3 | in treating their patients? A. What doctors? |
| | | 4 | |
| 5 | That's what they say, correct? A. The first sentence there, which is | | |
| | what I disputed. | 6 | A. Well, if they're already treating |
| 7 | Q. You disagree with that? | | them for ovarian cancer, it doesn't this |
| 8 | A. I correct. | | doesn't relate to that. This doesn't provide |
| 9 | Q. And with regard to the Gertig study, | | guidance on treatment approaches for it. |
| - | which you thought they intended to reference, that | 10 | Q. Is it your opinion that the summary |
| | study, as we looked at earlier, reported no | | that is in the NCI PDQ about perineal talc |
| 1 | overall association between epithelial ovarian | | exposure and ovarian cancer is not a reliable |
| 1 | cancer and ever use of talc, correct? | | summary? |
| 14 | A. They reported a 1.09 relative risk | 14 | A. Yes, I would agree with that. |
| | with a confidence interval of 0.86 to 1.37, which | 15 | Q. You can put that document aside for |
| 1 | suggests that the risk falls somewhere between | 16 | _ |
| l | there. | 17 | You make reference in your report |
| 18 | Q. Going back to the Board that we | 18 | MR. TISI: How long have we |
| | talked about earlier, the NCI PDQ Board. | 19 | been on the record? |
| 20 | A. Yes. | 20 | MR. HEGARTY: You want to take |
| 21 | Q. Is it your contention that they | 21 | a break? |
| | failed in their responsibility to doctors to put | 22 | MR. TISI: I just want to take |
| 1 | out accurate statements about the risk factors for | 23 | every hour or so. |
| l | ovarian cancer, in particular perineal talc | 24 | MR. HEGARTY: Sure. Let's go |
| | | | |
| l | Page 291 | | Page 293 |
| 1 | Page 291 exposure? | 1 | Page 293 off the record. |
| 1 2 | Page 291 exposure? A. I | 1 2 | off the record. |
| | exposure? | | off the record. (Recess: 2:58 p.m |
| 2 | exposure? A. I | 2 | off the record. |
| 3 | exposure? A. I MR. TISI: Objection. | 2 3 | off the record. (Recess: 2:58 p.m 3:10 p.m.) |
| 2 3 4 | exposure? A. I MR. TISI: Objection. THE WITNESS: Well, I believe | 2 3 4 5 | off the record. (Recess: 2:58 p.m 3:10 p.m.) MR. HEGARTY: We are back on |
| 2 3 4 5 | exposure? A. I MR. TISI: Objection. THE WITNESS: Well, I believe I went through the error besides the | 2 3 4 5 | off the record. (Recess: 2:58 p.m 3:10 p.m.) MR. HEGARTY: We are back on the record. |
| 2 3 4 5 6 | exposure? A. I MR. TISI: Objection. THE WITNESS: Well, I believe I went through the error besides the issue that I may have misinterpreted, | 2 3 4 5 6 7 | off the record. (Recess: 2:58 p.m 3:10 p.m.) MR. HEGARTY: We are back on the record. BY MR. HEGARTY: |
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| 1 | Page 294 | 1 O Are you aware though that the | Page 296 |
|--|---|---|------------------------|
| 1 | was assuming they were referring to Gertig because that was the original. | 1 Q. Are you aware, though, that the 2 was a follow-up study | ere |
| $\frac{2}{3}$ | I didn't but, in fact, in this, | 3 MR. TISI: Do you need the | |
| | which is very confusing, they talk about the | 4 article? | |
| | original report as being O'Brien. But that wasn't | 5 THE WITNESS: No, I have | t |
| 1 | the original report. Because the sentence before | 6 BY MR. HEGARTY: | |
| | that was talking about Woolen. | 7 Q. Are you aware that there was a | |
| 8 | So they talk about Woolen finding | 8 follow-up study done reported with the fi | |
| | the 1.47, but then they say "The subset analysis | 9 author of Gates in 2010 that had 10 more | |
| 1 | of the prospective study," which they say was | 10 data from the Nurses' Health Study? | y cars or |
| | was done by which was the prospective | 11 A. Yes. | |
| | "The subset analysis of the prospective study was | 12 Q. Have you read the Gertig I'm | |
| 1 | inconsistent with the main findings of the | 13 sorry the Gates 2010 study? | • |
| 1 | original report." | 14 A. I believe I did. | |
| 15 | Well, when you talk about the | 15 MR. HEGARTY: I've marke | d as |
| | original report, there's no reference to O'Brien's | 16 Exhibit Number 20 that study. | a us |
| 1 | report here. The reference should be to maybe | 17 THE WITNESS: Yeah. | |
| 1 | they didn't mean it to be original report, but | 18 (Document marked for | |
| 1 | that's the reason why I thought it should have | identification as Harlow Exhibit 20.) | |
| 1 | been Gertig and not O'Brien. | 20 BY MR. HEGARTY: | |
| 21 | Q. Okay. | 21 Q. Have you read Exhibit Number | 10. the |
| 22 | A. And that was my that was the | 22 Gates 2010 study? | 10, 1110 |
| | confusion there. | 23 A. Yes. | |
| 24 | | Q. Exhibit 20. I'm sorry. | |
| | Page 295 | | Page 297 |
| 1 | You make reference in your report at | 1 A. Yes, I know that I had revie | - |
| 2 | several places to the finding from the Gertig | 2 this. | |
| 3 | study about the relative risk or, I should say, | 3 Q. So have you read Exhibit N | lumber 20, |
| 4 | odds ratios reported for serous cancer, correct? | 4 the Gates 2010 study? | |
| 5 | A. Yes. | 5 A. Yeah, I have it in front of n | ne. |
| 6 | Q. The authors, as you know, reported | 6 Yes. | |
| 7 | an odds ratio of 1.40 from that 2000 Gertig study, | Yes, I had read that. | |
| 8 | correct? | 8 Q. Please turn over to Table 4 | on page |
| 9 | A. Let me just just give me a moment | 9 50 of that study. | |
| 10 | to to get the Gertig study open and take a | Tell me when you're there. | |
| 11 | look. | 11 A. I'm there. | |
| 12 | Okay. So now can you repeat the | 12 Q. The authors reported that a | s to talc |
| 1 | question? | 13 and serous invasive ovarian cancer, the | ne relative |
| | O. Sure. | 14 risk they found 10 years later with 10 | |
| | Q. Sure. | 14 Tisk they found to years fater with to | years |
| 13 | You make reference in your report | 15 additional data was 1.06 with a confid | • |
| 13 14 | You make reference in your report | • | • |
| 13 14 15 | You make reference in your report | 15 additional data was 1.06 with a confid | dence |
| 13 14 15 16 17 | You make reference in your report A. Oh, in my report. | 15 additional data was 1.06 with a confidenterval of .84 to 1.35, correct? 17 A. That is correct, but it's only dichotomous of exposure, greater that | dence for |
| 13 14 15 16 17 | You make reference in your report A. Oh, in my report. Q to the finding from Gertig of 1.04 odds ratio for serous adenocarcinoma. | 15 additional data was 1.06 with a confident of 1.84 to 1.35, correct? 17 A. That is correct, but it's only dichotomous of exposure, greater that 19 week or less than once per week. | for n once per |
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| | P 200 | | Pr 200 |
|--|--|--|---|
| 1 | Page 298 about that, greater than let me just see. Let | 1 | Page 300 the exposures that they that they chose to look |
| | me look. | | at with regard to talcum powder use and serous |
| 3 | "Estimates were adjusted for all | | invasive ovarian cancer, correct? |
| | variables." | 4 | A. Yes. Yes. |
| 5 | Well, I don't know whether the less | 5 | |
| | | | Q. That number is quite different than |
| | than once per week includes those who were | | the 1.40 number that you reference in your report |
| | unexposed as well. | | from Gertig 2000, correct? |
| 8 | I'm just looking to see if that's | 8 | MR. TISI: Objection. |
| | the case. | 9 | THE WITNESS: Well, it's |
| 10 | Because if it does not, if it if | 10 | again, it's it's different, but it's a |
| 1 | it mixes together those who were unexposed with | 11 | shifting down of the association because |
| 1 | those who were exposed less than once a week, then | 12 | of the mixing of the effects of exposed |
| | it would naturally attenuate the association. | 13 | and unexposed in the in the reference |
| 14 | Q. In preparing your report, you did | 14 | grouping. |
| | not make reference to this finding from Gates, | | BY MR. HEGARTY: |
| | correct? | 16 | Q. Have you done any analysis as to |
| 17 | A. No, I didn't. I don't believe I | | what that mixing effect had on the overall number? |
| - | did. | 18 | A. I don't need to do that. Because if |
| 19 | Q. Did you consciously make a decision | | you believe that that and as it's been shown |
| | not to refer to this finding from the Gates 2010 | | in a number of studies that any use of talc is |
| | study? | l . | associated with about 1.3 excess risk, if you take |
| 22 | A. I did not consciously make that | | some of those people who were exposed and put them |
| | decision. It's there's no new data. All it was | | into the reference group, it's going to attenuate |
| 24 | was additional it was additional follow-up | 24 | the association. |
| | | | |
| | Page 299 | | Page 301 |
| | period of time. | 1 | Q. There are a number of studies that |
| 2 | period of time. Q. Isn't this, though, at least some | 2 | Q. There are a number of studies that you don't cite that found as far as for serous |
| 3 | period of time. Q. Isn't this, though, at least some data that is contrary to the 1.4 odds ratio | 2 3 | Q. There are a number of studies that you don't cite that found as far as for serous adenocarcinoma, serous invasive adenocarcinoma, no |
| 2 3 4 | period of time. Q. Isn't this, though, at least some data that is contrary to the 1.4 odds ratio finding from the Gertig 2000 paper as it relates | 2 3 4 | Q. There are a number of studies that you don't cite that found as far as for serous adenocarcinoma, serous invasive adenocarcinoma, no statistically significant increase in risk. Those |
| 2 3 4 | period of time. Q. Isn't this, though, at least some data that is contrary to the 1.4 odds ratio finding from the Gertig 2000 paper as it relates to serous invasive tumors? | 2 3 4 | Q. There are a number of studies that you don't cite that found as far as for serous adenocarcinoma, serous invasive adenocarcinoma, no statistically significant increase in risk. Those include Houghton. They include the O'Brien study. |
| 2 3 4 | period of time. Q. Isn't this, though, at least some data that is contrary to the 1.4 odds ratio finding from the Gertig 2000 paper as it relates to serous invasive tumors? A. Let me look at the Gertig. | 2 3 4 | Q. There are a number of studies that you don't cite that found as far as for serous adenocarcinoma, serous invasive adenocarcinoma, no statistically significant increase in risk. Those |
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- When we interrupted -- when we broke 1 Q. 2 very quickly, I had a question pending. Let me 3 restate that.
- 4 A. Please.
- 5 O. Are you aware that some studies have
- 6 reported odds ratios of relative risk for talcum
- 7 powder use and serous invasive ovarian cancer that
- 8 were not statistically significant?
- 9 Oh. Yes.
- 10 O. Those included the WHI Houghton
- 11 study, correct?
- 12 Yes, but I might want to point out
- 13 that their association was pretty much consistent
- 14 with what we've seen in the other studies, being
- 15 1.13 as an association with a confidence interval
- 16 of 0.84 to 1.51 and in the -- and that's in the
- 17 WHI, which in and of itself I've already suggested
- 18 underestimates the association because of the fact
- 19 that they only include women 50 years of age and
- 20 older.
- 21 And then in the O'Brien study,
- 22 actually, if you look at the serous for frequent
- 23 users, it's got a confidence interval of 0.9 to
- 24 1.28. So, again, that's also -- that's also
- Page 303

1

- 1 comparable given that they're mixing in in this
- 2 study, the WHI and the Sister Study, which have
- 3 significant exposure assessment flaws.
- Both of those point estimates that
- 5 you cite to are not statistically significant,
- 6 correct?
- A. They -- the confidence interval
- 8 includes 1, but it doesn't mean that it's a null
- 9 association.
- 10 Where a confidence interval Q.
- 11 includes 1, the result could be due to chance,
- 12 correct?
- 13 A. Well, even a confidence interval
- 14 that doesn't include 1 could be due to chance.
- But a confidence interval that
- 16 includes 1 means that the real point estimate
- 17 could be 1.0?
- It could be 1.0, but it's not likely 18
- 19 to be skewed toward the lower end. It's likely to
- 20 be somewhere in the middle.
- You don't reference anywhere --21
- 22 anywhere in your report the serous invasive
- 23 findings from Houghton or from O'Brien, correct?
- 24 I'd have to look in -- I'd have to Α

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- 1 look in my report for those particular reviews,
- 2 but let me just quickly do that if I may.
- 3 So for the Women's Health
- 4 Initiative, yes, I do. Multivariate adjusted
- 5 hazard ratio for serous ovarian tumors was 1.16
- 6 with a confidence interval of 0.88 to 1.53.
- 7 And for -- I'm sorry. What was the
- 8 other one?
- 9 O'Brien 2020. Q.
- 10 A. Oh, yeah.
- And for O'Brien, I don't believe I 11
- 12 -- I don't talk about that one in my summary in
- 13 the report.
- 14 Let me ask you some basic Q.
- 15 information, or let me ask you about some basic
- 16 information.
- 17 Α. Yeah.
- 18 0. The cancer at issue, as we've been
- 19 talking about, is ovarian cancer, correct?
- 20 The cancer at issue is the ovarian
- 21 cancer, yes.
- 22 You have not been involved in the
- 23 care and treatment of any patient who has had
- 24 ovarian cancer, correct?

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- A. I am not a physician.
- 2 Q. You have no medical training in
- 3 gynecologic oncology, correct?
- 4 That is correct. A.
- 5 Q. You have no expertise in diagnosing
- 6 ovarian cancer, correct?
- 7 A. I am not a clinician.
- 8 You have no expertise in diagnosing Q.
- 9 mesothelioma, correct?
- 10 A. Correct.
- 11 You have no expertise in analyzing a
- 12 patient's risk factors for ovarian cancer,
- 13 correct?
- 14 Let me ask it a different way.
- 15 You have never analyzed a patient's
- 16 risk factors for ovarian cancer outside of work
- 17 you've done for litigation, correct?
- 18 A. Correct.
- 19 MR. TISI: Object.
- 20 BY MR. HEGARTY:
- 21 Outside of litigation, you've never
- 22 attempted to look at a particular patient's
- 23 various risk factors and identify which, if any,
- 24 may have contributed to the development of her

| Page : | Page 308 |
|---|---|
| 1 ovarian cancer, correct? | 1 A. That is a fair statement. |
| 2 A. I've always worked at the population | 2 Q. You're also not an expert on animal |
| 3 level. | 3 studies, true? |
| 4 Q. Outside of perhaps the cases you've | 4 A. That's true. |
| 5 consulted on for litigation, you never came to the | 5 Q. You're not an expert on cell |
| 6 opinion that talc caused any woman's ovarian | 6 studies, correct? |
| 7 cancer, correct? | 7 A. That's true. |
| 8 MR. TISI: Objection. | 8 Q. Do you consider yourself an expert |
| 9 THE WITNESS: I have not | 9 on talc as a mineral? |
| published any or made any kind of | 10 A. I consider myself an expert on the |
| statement regarding that. | 11 epidemiologic data looking at the association |
| 12 BY MR. HEGARTY: | 12 between talc and ovarian cancer. |
| 13 Q. And regardless of publishing or | Q. Do you consider yourself an expert |
| 14 making any statement, you have not concluded, ev | |
| 15 where you have not shared it with anyone, that any | |
| 16 particular patient's ovarian cancer was caused by | 16 A. No, I do not. |
| 17 talcum powder use, correct? | 17 Q. You are not a geneticist, correct? |
| 18 A. No, because I would not have been in | 18 A. That is correct. |
| 19 position to do that. | Q. You're not a mineralogist, correct? |
| Q. You also never came to the opinion | 20 A. That is correct. |
| 21 that any woman's exposure to asbestos caused her | Q. You're not an industrial hygienist, |
| 22 ovarian cancer, correct? | 22 correct? |
| 23 A. I have not been in position to do | 23 A. That's correct. |
| 24 that. | Q. You're not an expert in geology, |
| | |
| Page | _ |
| 1 Q. And you've never told a patient that | 1 correct? |
| 1 Q. And you've never told a patient that 2 her talc use caused her ovarian cancer, correct | 1 correct? 2 A. No. |
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| Page 310 | Page 312 |
|--|---|
| 1 Q. And in that course on "Guided | 1 Q. We've talked a little bit about |
| 2 Epidemiology Research," did you go through th | 2 statistical significance. |
| 3 methodology you describe in your report? | 3 You agree that statistical |
| 4 A. Yes. The students come up, develop | 4 significance using a p-value of .05 is an |
| 5 a research question, analyze data for a particular | 5 important evaluation in an epidemiologic study? |
| 6 hypothesis, analyze the data, and then interpret | 6 A. No, I do not agree with that. |
| 7 the findings. And during the interpretation of | 7 It is an arbitrary dichotomous cut |
| 8 the findings, they go through the process of | 8 point that merely represents that the risk |
| 9 determining whether or not they believe the | 9 estimate 95 percent of the time will fall between |
| 10 findings to be true or spurious based on the sam | _ |
| 11 criteria that I used in determining the the | 11 bound. And if that lower confidence bound is 0.99 |
| 12 scientific integrity of the talc and ovarian | 12 and the upper confidence bound is 1.45, then to |
| 13 cancer association. | 13 deem it not statistically significant is |
| Q. What level of student did you teach | 14 inappropriate. |
| 15 that to? | 15 Q. Is a p-value of .05 still the |
| 16 A. These are master's level students. | 16 standard for determining whether a study shows an |
| Q. Outside of your presentation to FDA | 17 association between an exposure and a disease? |
| 18 at the workshop back in 1994, have you ever | 18 A. It is a tool that is used, but not |
| 19 lectured to your peers with regard to your | 19 one that is relied upon for assessing causation. |
| 20 opinions on talc and ovarian cancer? | 20 Q. Going back to my question, though. |
| 21 A. I may have given a seminar on the | 21 From your standpoint, is it still an |
| 22 research because I have a body of research that | 1 |
| 23 had done at that time, but certainly not recently. | 23 association between an exposure and a disease? |
| 24 Q. You say | MR. TISI: Objection to the |
| | |
| Page 311 | Page 313 |
| Page 311 1 A. And I can't think of any, and you | Page 313 1 term "industry standard." This is a |
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Page 314 Page 316 1 BY MR. HEGARTY: 1 A. With the exposure, yes. The 2 exposure of interest and the outcome, yes. 2 Going back to the null value of 1. 3 In every study there exists the 3 If the confidence interval contains the value of 4 potential for unknown confounders, correct? 4 1, then the true finding, as I mentioned earlier, 5 A. Yes, possibly. 5 could be 1.0, correct? 6 Q. When considering bias and 6 A. The true value could be anywhere 7 confounders, the weaker the association, that is, 7 from the lowest confidence bound to the highest 8 confidence bound. 8 the closer it is to 1.0, the greater the concern 9 is that bias or confounding could be the reason Q. Do you agree that there are 10 generally three categories of phenomena that could 10 for that association, correct? 11 result in an association finding in a study to be 11 Yes, certainly greater -- I mean, 12 attention should be paid regardless of whether it 12 erroneous: chance, bias, and confounding? 13 is an association of 1.3, 2.0, 3.0. We always use 13 A. Well, confounding is bias. So 14 the same method to determine how reliable that 14 chance is certainly one. Confounding is certainly 15 one. But within the category of bias, there are a 15 estimate is based on potential sources of bias --16 number of different components that are there, 16 Q. And association --17 such as misclassification, selection bias, things 17 A. -- and confounding. 18 O. Finding association does not mean 18 like that. 19 causation, correct? 19 Is there any way to account for 20 A. 20 chance in an epidemiologic study besides That is correct. 21 A risk factor is not necessarily a 21 statistical significance? 0. 22 MR. TISI: In an individual 22 causal factor, correct? 23 A. That is correct. 23 study or in studies overall? Going back to your methodology 24 BY MR. HEGARTY: 24 Q. Page 315 Page 317 1 Q. Well, did you understand my 1 section in your report. 2 2 question? Α. Uh-huh. 3 3 What is the objective criteria that A. Why don't --4 MR. TISI: I need to 4 you apply for this methodology? 5 5 MR. TISI: Objection. Asked understand it. It needs to be clear. So 6 is it --6 and answered a couple times. 7 You may answer it again. 7 BY MR. HEGARTY: 8 Is there any way in an epidemiologic 8 BY MR. HEGARTY: 9 study to account for chance other than through 9 Let me put -- let me ask a different 10 statistical significance? 10 way because that may be unclear. Isn't your methodology subjective 11 MR. TISI: Objection. 11 12 THE WITNESS: Accounting for 12 based on the person who's conducting it? And if 13 -- statistical significance is not a way 13 so -- if not, why not? 14 14 to determine whether chance is the MR. TISI: Objection. Asked 15 explanation for the finding. 15 and answered a couple times. 16 The way to determine whether 16 THE WITNESS: I wouldn't -- I 17 chance is the explanation for the finding 17 wouldn't say it's subjective. 18 is to look at other known factors that 18 I would say it's objective. 19 could be influencing the association. 19 There's no qualitative process. I mean, 20 BY MR. HEGARTY: 20 it's -- it's evaluation of quantitative Confounding is where there could be 21 21 data. 22 another association present within the study that 22 So looking at the strength of 23 confuses the relationship between the agent of 23 the association in terms of the -- the 24 interest and the outcome of interest, correct? 24 range in which the confidence interval,

| | Page 318 | | Page 320 |
|----|---|----|---|
| 1 | the estimate falls; looking at the extent | 1 | could have been present, and even those that may |
| 2 | possible whether there's an increasing | | be unrecognized. |
| 3 | association with increasing levels of | 3 | Q. You told me that you applied this |
| 4 | exposure, whether there's biological | | methodology in your studies on talc and ovarian |
| 5 | plausibility and potential for explaining | 5 | cancer? |
| 6 | the association, whether there's a | 6 | A. Yes. |
| 7 | temporal issue, and whether there is | 7 | Q. Let me ask in a different way. |
| 8 | consistency across multiple studies is | 8 | Have you ever described the process |
| 9 | certainly a standard that we do, in | | of this methodology, without regard to the |
| 10 | conjunction with trying to explain other | | exposure and the disease you're looking at, in an |
| 11 | non-causal explanations for all of those | | written publication of yours? |
| 12 | findings. | 12 | A. No. |
| 13 | So I believe that's that's | 13 | MR. TISI: Objection. |
| 14 | my response to your question. | 14 | THE WITNESS: No, I haven't, |
| 1 | BY MR. HEGARTY: | 15 | but it is a standard of practice that's |
| 1 | | | • |
| 16 | Q. Turn over to page 5 of your report. | 16 | indicated in epidemiology methods |
| 17 | A. Yes. | 17 | textbooks in the approach. |
| 18 | Q. At the very top. | 18 | It is the foundation of |
| 19 | A. Yes. | 19 | epidemiologic research. |
| 20 | Q. You write that: | | BY MR. HEGARTY: |
| 21 | "The point is that epidemiologists | 21 | Q. Is this methodology, as you can |
| | make their inferences by pitting alternative | | recall, described in Dr. Rothman's textbook? |
| 1 | explanations against one another. This approach | | A. Yes. Certainly all these components |
| 24 | amounts to pitting non-causal theories against a | 24 | related to the biases. |
| | Page 319 | | Page 321 |
| 1 | causal theory. Epidemiologists ask, 'Is there | 1 | Q. Please turn over to paragraph 20 |
| 1 | some systematic error in the data from a study? | | I'm sorry to page 20 of your report. |
| 1 | Then let's control that problem to see what | 3 | A. Yes. |
| 1 | association if any remains between exposure and | 4 | Q. Do you cite at the top the factors |
| | disease." | 5 | that you rely upon for reaching your opinions in |
| 6 | Did I read that correctly? | | this case? |
| 7 | A. You did. | 7 | A. Uh-huh. |
| 8 | Q. So is it so are you saying there | 8 | Q. Yes? |
| 9 | that there is an association that an | 9 | A. Yes. |
| 1 | association is causal unless it can be explained | 10 | Q. We talked about this a little bit |
| 11 | by some systematic error? | | earlier, but at the top of page 20 you say that |
| 12 | A. It may very well be causal if after | | "Considering the preponderance of the evidence, |
| | all well, it may be assumed to be causal after | | including" and then you cite prepared at B |
| 1 | explaining all of the potential explanations for | 14 | A. I'm sorry. Where is this? The |
| | the association, and that includes systematic | | sentence? |
| 16 | error in the data. | 16 | Q. Yeah. Very top. |
| 17 | Q. Is that how you reached your | 17 | A. Oh, "Considering." Yes, yes, yes. |
| 18 | opinions in this case, by controlling or | | Yes. |
| 19 | accounting for systematic error? | 19 | Q. "Including" and then going to |
| 20 | A. We we didn't quantitatively do | 20 | paragraph B. |
| 21 | that. We looked to see if it had been done in the | 21 | "After controlling for known risk |
| 22 | studies and made our assessments based on issues | | and protective factors for ovarian cancer, |
| 23 | related to to misclassification of the exposure | 23 | evidence of a trend of increasing risk of ovarian |
| 24 | and confounding and other sources of bias that | 24 | cancer with increasing talc applications, |
| | | 24 | cancer with increasing talc applications, |

Page 322 Page 324 Well, in the O'Brien study that 1 especially when the vaginal tract is open to the 1 2 ovaries." 2 looked at all the cohort studies together, they 3 You see where I'm reading? 3 recognized that the association was, in their 4 Yes, I do. 4 view, statistically significant in those with A. 5 And that evidence of a trend that 5 patent genital tracts, and that's a compilation of O. 6 all three of the cohort studies, despite the fact 6 you specifically refer to in your report is from 7 the Cramer 2016 study, correct? 7 that the cohort studies are flawed in terms of MR. TISI: Objection. 8 8 exposure assessment. 9 THE WITNESS: Close. It's 9 If we look at the findings in the 10 from multiple studies. There is the 10 cohort studies as to ovarian cancer and talc use Cramer study. There's my 1992 study. 11 overall, none of those studies reported a 11 12 There's Schildkraut study. There's a 12 statistically significant association between talc 13 number of studies that have shown this. 13 use ever never and ovarian cancer, correct? 14 BY MR. HEGARTY: 14 MR. TISI: Objection. 15 And you mentioned Schildkraut. Let 15 THE WITNESS: Well, that's 16 me clarify my question. 16 correct, but it's largely because the 17 A. Yeah. 17 associations that as we talked about in 18 O. The only two studies you actually 18 our report are attenuated because of the 19 specifically refer to in your report as shown as 19 issue of misclassification. 20 being a preponderance of the evidence are the 20 And particularly the issue 21 Cramer and Schildkraut studies, correct? 21 of -- of selection bias, such as in the 22 That's what's listed in the report. 22 Sister Study where 160 or so women with 23 Although in the description of the meta-analyses, 23 ovarian cancer were excluded from the 24 there may have been some discussion of dose analyses because they already had ovarian 24 Page 323 Page 325 1 response. But those are not new data, and this is 1 cancer, and they only followed up those 2 new data. The other ones are meta-analyses. 2 who hadn't already had ovarian cancer 3 Please turn over to the Executive and, therefore, you have a depletion of 4 Summary section of your report, which is on 4 susceptibles in that and so you wouldn't 5 5 page 6. -- you would already be underestimating 6 6 A. Uh-huh. the risk. O. Second paragraph, the middle of that 7 And the WHI, as I indicated, 8 paragraph you make the sentence -- you make the 8 had women who weren't enrolled in the 9 statement: 9 study until after age 50. About half of 10 "We note that there is also an 10 ovarian cancers occur before the age of 11 association between talc use and ovarian cancer in 11 50. 12 cohort studies." 12 So, so I'm not surprised that Do you see where I'm reading? 13 the associations are attenuated in the 13 14 A. 14 cohort studies. 15 Do any of the cohort studies 15 BY MR. HEGARTY: O. 16 themselves say that there is an association 16 Can you cite for me any author in 17 between talc use and ovarian cancer? 17 any published literature who has said that the 18 Yes, the Nurses' Health Study shows 18 cohort studies showed an association between talc 19 it. 19 use and ovarian cancer? 20 Q. My question, though, is very 20 Other than in the Gertig article 21 where they did say for those -- those with a --21 specific. My question is: Do the authors 22 with serous tumors had an association they thought 23 state in their studies that they show an 23 was statistically significant, I believe. Yeah. 24 association between talc use and ovarian cancer? 24 Q. Anywhere else besides Gertig as to

| | Page | Page : |
|--|---|--|
| 1 | serous invasive ovarian cancer? | 1 was not statistically significant, correct? |
| 2 | A. And the joint analysis that O'Brien | 2 A. The confidence interval did include |
| 3 | did with respect to patent open patent tracts | |
| 4 | Q. In your "Case-control studies" | 4 hospital control use of hospital controls can |
| 5 | section at page 8, you talk about the lengths - | |
| 6 | | 6 for them being in the hospital could be related or |
| 7 | A. Under "Case-control studies"? | 7 could be a confounding factor on things that |
| 8 | Q. Yes, page 8. | 8 influence women's gynecologic cancers. |
| 9 | A. Oh, I'm sorry. | 9 So, you know, I'm not surprised |
| 10 | Q. At the top. | 10 that that we see a little bit of a difference |
| 11 | A. Yes. | 11 there. |
| 12 | MR. HEGARTY: I'm going to | 12 Q. You had done hospital-control |
| 13 | show you the Langseth 2008 study, which | |
| 14 | | 14 studies? |
| 15 | (Document marked for | 15 A. Most of my research has been |
| 16 | • | 16 population-based. I'm trying to think about my |
| 17 | THE WITNESS: Yeah. Yep. | 17 study in 1989. I know that was cancer |
| | BY MR. HEGARTY: | 18 population-based cases. Did I use? |
| 19 | Q. In this study, the authors reported | Because all my other research |
| | heterogeneity between the hospital and the | 20 outside of ovarian cancer has been |
| 21 22 | population-based studies, correct? | 21 population-based, but let me just see in the |
| 23 | A. Yes.Q. That means that the combined result | 22 those tumors. Let me see. |
| | of those studies were different from a statistic | , |
| 24 | | |
| | Page | 327 Page 1 |
| 1 | _ | |
| | standpoint, correct? | 1 Q. Okay. |
| 2 | standpoint, correct? A. Oh, can I see the the exhibit? | Q. Okay. A. So I've really done all |
| 3 | standpoint, correct? A. Oh, can I see the the exhibit? Oh, here we go. | Q. Okay. A. So I've really done all population-based research. |
| 2 3 4 | standpoint, correct? A. Oh, can I see the the exhibit? Oh, here we go. Q. Take a look at Figure 1. | Q. Okay. A. So I've really done all |
| 2 3 4 5 | standpoint, correct? A. Oh, can I see the the exhibit? Oh, here we go. Q. Take a look at Figure 1. A. Yeah, here we go. | Q. Okay. A. So I've really done all population-based research. Q. Did you read the Langseth article when it came out in 2008? |
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| 2 3 4 5 6 7 | standpoint, correct? A. Oh, can I see the the exhibit? Oh, here we go. Q. Take a look at Figure 1. A. Yeah, here we go. Right. Right. So the question? Q. Let me start ask it a different | Q. Okay. A. So I've really done all population-based research. Q. Did you read the Langseth article when it came out in 2008? A. Not in 2008. Q. Had you read it prior to being contacted by plaintiffs' counsel in this case |
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| | Page 330 | | Page 332 |
| 1 | studies, particularly the | 1 | about this or should be told to look for |
| 2 | population-based studies, which are the | 2 | alternative methods. |
| 3 | ones that are more of a gold standard | 3 | I believe in 1999 I may have made |
| 4 | approach for epidemiological research, | 4 | the same recommendations. I even raised concerns |
| 5 | every one of the estimates are above 1 | 1 | in 1989. |
| 6 | with a very narrow confidence interval of | 6 | So have I do we need to have |
| 7 | 1.3 to 1.5. | 7 | definitively determined causation in order for us |
| 8 | So to say that the current | | to have informed women of the risk, potential risk |
| 9 | body of epidemiologic evidence is | | of using a product that had no reasonable |
| 10 | | | that that was not therapeutic or necessary with |
| 11 | The experimental I can't I can't, you | | an alternative available? I think I did my best |
| 12 | know, make a comment on. | | to try to provide that warning. |
| | BY MR. HEGARTY: | 13 | MR. HEGARTY: I want to next |
| 14 | | 14 | show you a study with a first author |
| | side of page 359. | 15 | Rosenblatt dated from 2011 I marked as |
| 16 | | 16 | Exhibit Number 22. |
| 17 | Q. The middle paragraph. | 17 | (Document marked for |
| 18 | A. Yes. | 18 | identification as Harlow Exhibit 22.) |
| 19 | Q. Towards the bottom. They make the | 19 | THE WITNESS: Yes, thank you. |
| | statement that: | 20 | Let me see if I have |
| 21 | "The main epidemiological evidence | 21 | Rosenblatt in here. Yeah. |
| | against the association is the absence of clear | | BY MR. HEGARTY: |
| | exposure-response associations in most study, as | 1 | Q. You read the Rosenblatt study as |
| | well as the absence of an overall excess risk in | | part of your work on this case; is that correct? |
| | | ļ | |
| 1 | Page 331 the cohort study." | 1 | Page 333 A. I did, but I'm trying to see if it's |
| 2 | Were those true statements back in | | cited. I don't know that it was cited in my |
| | 2008? | | report. So let's just see if it was. |
| 4 | A. I'm not sure what they mean by | 4 | No. I'm aware of this study. I'm |
| - | "exposure-response," which I think they mean is | | aware of this study, but I did not it was not |
| | with increasing exposure, you see a greater risk | | in my in my report. |
| | of the disease. | 7 | Q. One of the authors of the study is |
| 8 | And, again, my article in 1992, in | | Noel Weiss? |
| | 1999, other articles that have shown a dose | 9 | A. That's correct. |
| | response are not were present. | 10 | Q. He is your primary mentor, correct? |
| 11 | So could we have more? Yes, I'd | 11 | A. He was, correct. |
| | love there to have been more. But is there enough | 12 | Q. He was your primary mentor, correct |
| | for us to be concerned about this exposure? Yes. | 13 | A. Yes, he was. |
| 14 | And then and then the absence of | 14 | Q. How would you characterize his |
| | an overall excess risk in the cohort study, I've | 1 | capabilities as an epidemiologist? |
| | talked about that. | 16 | A. Outstanding. |
| 17 | Q. Have you done an analysis of when | 17 | Q. Is he a reliable was he a |
| | you believe the evidence was sufficient over the | 1 | reliable authority with regard to epidemiology? |
| | years to say that there was there is was a | 19 | A. With respect to epidemiology? Yes. |
| | causal relationship or there is a causal | 20 | Q. Did you read the Rosenblatt study at |
| | relationship between talc use and ovarian cancer? | $\begin{vmatrix} 20 \\ 21 \end{vmatrix}$ | the time it came out in 2011? |
| 22 | A. I did not do a causal inference | $\begin{vmatrix} 21\\22\end{vmatrix}$ | A. I can't recall if I did. |
| | analysis; but in my papers, particularly 1992, I | 23 | Q. You said he was your mentor. |
| | believe I recommended that women should be warned | 1 | Was he one of your teachers? |
| ۷4 | ocheve i recommended that women should be warned | | vv as the one of your teachers! |

| Page 334 | Page 336 |
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| 1 A. Yes, and he was my dissertation | 1 and in some previous ones, but that association |
| 2 advisor. | 2 generally has not been consistent within or among |
| 3 Q. So you had great respect for him? | 3 studies. Therefore, no stronger adjective than |
| 4 A. Yes, I do. | 4 'possible' appears warranted at this time." |
| 5 Q. Looking in the "Abstract" of this | 5 Do you disagree with those |
| 6 paper, that looked at genital powder exposure and | 6 conclusion statements? |
| 7 the risk of epithelial ovarian cancer. | 7 A. Oh, not I don't necessarily |
| 8 A. Uh-huh. | 8 disagree with it, but this was in 2011 and there |
| 9 Q. Towards the bottom. | 9 have been a number of studies and meta-analyses |
| 10 A. Uh-huh. | 10 that have been done since then. |
| 11 Q. The authors, including Dr. Weiss, | 11 Q. Were these true statements back in |
| 12 say: | 12 2011? |
| "We noted no clear pattern of risk | 13 A. In terms of saying that "possible |
| 14 increase on the basis of the extent of use, | 14 appears warranted at this time"? I would have |
| 15 assessed as years in which powder was used, or as | 15 been a little bit stronger in my term. |
| 16 lifetime number of applications for invasive or | 16 Q. What stronger term would you have |
| 17 borderline tumors, or their histologic subtypes." | 17 used? |
| That's a correct statement from what | 18 A. Feasible, but I'm okay with that. |
| 19 their data showed, correct? | 19 Q. Turning over to page 739. |
| 20 A. Actually | 20 A. Yes. |
| 21 MR. TISI: Objection. Please | 21 Q. In the "Results" section on the |
| take a moment and look at the study. | 22 right-hand column, first full paragraph. The |
| THE WITNESS: No, I'm looking | 23 authors write: |
| 24 at it, and I can tell you that for all | 24 "We noted no evidence that risk of |
| Page 335 | |
| 1 tumors, those who used powder after | 1 ovarian cancer increased in association with |
| 2 bathing had a 1.27 excess risk after | 2 increasing extent of the use of perineal dusting |
| 3 adjustment for, you know, the most | 3 powder (assessed as years in which powder was used 4 or as lifetime number of applications) for either |
| 4 important risk factors with a confidence | |
| 5 interval of 0.97 to 1.66. | ** ' |
| 6 DV MD HECADTV. | 5 invasive or borderline tumors." |
| 6 BY MR. HEGARTY: | 5 invasive or borderline tumors."6 Did I read that correctly? |
| 7 Q. The part of the abstract I read to | 5 invasive or borderline tumors." 6 Did I read that correctly? 7 A. Yes, you did. |
| 7 Q. The part of the abstract I read to 8 you, though, was in regards to dose response, | 5 invasive or borderline tumors." 6 Did I read that correctly? 7 A. Yes, you did. 8 Q. Is that an accurate summary of their |
| 7 Q. The part of the abstract I read to8 you, though, was in regards to dose response,9 correct? | 5 invasive or borderline tumors." 6 Did I read that correctly? 7 A. Yes, you did. 8 Q. Is that an accurate summary of their 9 evidence with regard to increasing with regard |
| 7 Q. The part of the abstract I read to 8 you, though, was in regards to dose response, 9 correct? 10 A. (Reviews document.) | 5 invasive or borderline tumors." 6 Did I read that correctly? 7 A. Yes, you did. 8 Q. Is that an accurate summary of their 9 evidence with regard to increasing with regard 10 to whether an association increased with the |
| 7 Q. The part of the abstract I read to 8 you, though, was in regards to dose response, 9 correct? 10 A. (Reviews document.) 11 Right, but they didn't take it | 5 invasive or borderline tumors." 6 Did I read that correctly? 7 A. Yes, you did. 8 Q. Is that an accurate summary of their 9 evidence with regard to increasing with regard 10 to whether an association increased with the 11 increasing extent of use? |
| 7 Q. The part of the abstract I read to 8 you, though, was in regards to dose response, 9 correct? 10 A. (Reviews document.) 11 Right, but they didn't take it 12 yes, but they did not take into account times when | 5 invasive or borderline tumors." 6 Did I read that correctly? 7 A. Yes, you did. 8 Q. Is that an accurate summary of their 9 evidence with regard to increasing with regard 10 to whether an association increased with the 11 increasing extent of use? 12 A. Yes, based on their data. Uh-huh. |
| 7 Q. The part of the abstract I read to 8 you, though, was in regards to dose response, 9 correct? 10 A. (Reviews document.) 11 Right, but they didn't take it 12 yes, but they did not take into account times when 13 the genital tract was open. They did not consider | 5 invasive or borderline tumors." 6 Did I read that correctly? 7 A. Yes, you did. 8 Q. Is that an accurate summary of their 9 evidence with regard to increasing with regard 10 to whether an association increased with the 11 increasing extent of use? 12 A. Yes, based on their data. Uh-huh. 13 Q. Please turn over to the "Discussion" |
| 7 Q. The part of the abstract I read to 8 you, though, was in regards to dose response, 9 correct? 10 A. (Reviews document.) 11 Right, but they didn't take it 12 yes, but they did not take into account times when 13 the genital tract was open. They did not consider 14 issues with respect to ovulation. They did not | 5 invasive or borderline tumors." 6 Did I read that correctly? 7 A. Yes, you did. 8 Q. Is that an accurate summary of their 9 evidence with regard to increasing with regard 10 to whether an association increased with the 11 increasing extent of use? 12 A. Yes, based on their data. Uh-huh. 13 Q. Please turn over to the "Discussion" 14 section on page 741. |
| 7 Q. The part of the abstract I read to 8 you, though, was in regards to dose response, 9 correct? 10 A. (Reviews document.) 11 Right, but they didn't take it 12 yes, but they did not take into account times when 13 the genital tract was open. They did not consider 14 issues with respect to ovulation. They did not 15 consider whether or not they had whether | 5 invasive or borderline tumors." 6 Did I read that correctly? 7 A. Yes, you did. 8 Q. Is that an accurate summary of their 9 evidence with regard to increasing with regard 10 to whether an association increased with the 11 increasing extent of use? 12 A. Yes, based on their data. Uh-huh. 13 Q. Please turn over to the "Discussion" 14 section on page 741. 15 A. Well, but if you also look in that |
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| 7 Q. The part of the abstract I read to 8 you, though, was in regards to dose response, 9 correct? 10 A. (Reviews document.) 11 Right, but they didn't take it 12 yes, but they did not take into account times when 13 the genital tract was open. They did not consider 14 issues with respect to ovulation. They did not 15 consider whether or not they had whether 16 exposures occurred before or after a tubal 17 ligation or hysterectomy. | 5 invasive or borderline tumors." 6 Did I read that correctly? 7 A. Yes, you did. 8 Q. Is that an accurate summary of their 9 evidence with regard to increasing with regard 10 to whether an association increased with the 11 increasing extent of use? 12 A. Yes, based on their data. Uh-huh. 13 Q. Please turn over to the "Discussion" 14 section on page 741. 15 A. Well, but if you also look in that 16 paragraph, risk was increased among women who 17 first reported the regular use of perineal dusting |
| 7 Q. The part of the abstract I read to 8 you, though, was in regards to dose response, 9 correct? 10 A. (Reviews document.) 11 Right, but they didn't take it 12 yes, but they did not take into account times when 13 the genital tract was open. They did not consider 14 issues with respect to ovulation. They did not 15 consider whether or not they had whether 16 exposures occurred before or after a tubal 17 ligation or hysterectomy. 18 Q. Please look at the "Conclusions" | 5 invasive or borderline tumors." 6 Did I read that correctly? 7 A. Yes, you did. 8 Q. Is that an accurate summary of their 9 evidence with regard to increasing with regard 10 to whether an association increased with the 11 increasing extent of use? 12 A. Yes, based on their data. Uh-huh. 13 Q. Please turn over to the "Discussion" 14 section on page 741. 15 A. Well, but if you also look in that 16 paragraph, risk was increased among women who 17 first reported the regular use of perineal dusting 18 powders at age 30 years or older. Odds ratio for |
| 7 Q. The part of the abstract I read to 8 you, though, was in regards to dose response, 9 correct? 10 A. (Reviews document.) 11 Right, but they didn't take it 12 yes, but they did not take into account times when 13 the genital tract was open. They did not consider 14 issues with respect to ovulation. They did not 15 consider whether or not they had whether 16 exposures occurred before or after a tubal 17 ligation or hysterectomy. 18 Q. Please look at the "Conclusions" 19 section in the abstract on page 1. | 5 invasive or borderline tumors." 6 Did I read that correctly? 7 A. Yes, you did. 8 Q. Is that an accurate summary of their 9 evidence with regard to increasing with regard 10 to whether an association increased with the 11 increasing extent of use? 12 A. Yes, based on their data. Uh-huh. 13 Q. Please turn over to the "Discussion" 14 section on page 741. 15 A. Well, but if you also look in that 16 paragraph, risk was increased among women who 17 first reported the regular use of perineal dusting 18 powders at age 30 years or older. Odds ratio for 19 invasive borderline tumors of 1.69 on women whose |
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| 7 Q. The part of the abstract I read to 8 you, though, was in regards to dose response, 9 correct? 10 A. (Reviews document.) 11 Right, but they didn't take it 12 yes, but they did not take into account times when 13 the genital tract was open. They did not consider 14 issues with respect to ovulation. They did not 15 consider whether or not they had whether 16 exposures occurred before or after a tubal 17 ligation or hysterectomy. 18 Q. Please look at the "Conclusions" 19 section in the abstract on page 1. 20 A. Uh-huh. 21 Q. The authors write, including | 5 invasive or borderline tumors." 6 Did I read that correctly? 7 A. Yes, you did. 8 Q. Is that an accurate summary of their 9 evidence with regard to increasing with regard 10 to whether an association increased with the 11 increasing extent of use? 12 A. Yes, based on their data. Uh-huh. 13 Q. Please turn over to the "Discussion" 14 section on page 741. 15 A. Well, but if you also look in that 16 paragraph, risk was increased among women who 17 first reported the regular use of perineal dusting 18 powders at age 30 years or older. Odds ratio for 19 invasive borderline tumors of 1.69 on women whose 20 first regular use was in 1980 or later, and there 21 they also showed a very strong association with |

| | Page 338 Page 34 |
|---|--|
| 1 Q. Those statements you describe | |
| 2 not pertain to dose response, correct? | 2 THE WITNESS: Yes. Yeah, |
| 3 A. Well, not not in the way in v | |
| 4 they did it, but it could indicate longer p | |
| 5 of time of exposure. | 5 Okay. Could you repeat the |
| 6 Q. Please look over to the "Discu | |
| 7 section. | 7 BY MR. HEGARTY: |
| 8 A. Uh-huh. | 8 Q. Sure. |
| 9 Q. The first paragraph, the author | |
| 10 write: | 10 I read beginning: |
| 11 "A number of case-control stud | |
| 12 ovarian cancer, in addition to ours, have | · · · · · · · · · · · · · · · · · · · |
| 13 the issue of genital powder exposure as a | |
| 14 potential risk factor. The validity of all | |
| 15 these studies, including ours, may be inf | |
| 16 by the level of non-response among case | |
| 17 controls, and by the potential for | 17 focusing on the overall association, when in that |
| 18 misclassification (differential and | 18 same article they provide exposure assessments in |
| 19 non-differential) of exposure status." | 19 different ways and more appropriate ways. So I |
| 20 Are those two accurate statement | , |
| 21 A. They're always possible. | 21 And then when they talk about the |
| 22 Q. Please turn over to the next pa | |
| 23 A. But I think it's important to po | |
| 24 out that when you make a statement like | |
| | |
| | |
| 1 should probably provide a little more inf | Page 339 Page 34 |
| 1 should probably provide a little more inf | formation 1 the multiple studies mine in particular in |
| 2 as to what those potential what potential | formation 1 the multiple studies mine in particular in 2 1992, 1999 as fact evidence. |
| 2 as to what those potential what potential 3 examples might be. | formation 1 the multiple studies mine in particular in 2 1992, 1999 as fact evidence. 3 So are we to make our decision on |
| 2 as to what those potential what potential 3 examples might be. 4 Q. Please turn over to the next page. | formation 1 the multiple studies mine in particular in 2 1992, 1999 as fact evidence. 3 So are we to make our decision on 4 causality based on one study? I don't believe so. |
| 2 as to what those potential what potential 3 examples might be. 4 Q. Please turn over to the next page. 5 The first full paragraph beginning | formation 1 the multiple studies mine in particular in 2 1992, 1999 as fact evidence. 3 So are we to make our decision on 4 causality based on one study? I don't believe so. 5 We look at it in the package of all studies that |
| 2 as to what those potential what potential 3 examples might be. 4 Q. Please turn over to the next pa 5 The first full paragraph beginning 6 "In support of." | formation 1 the multiple studies mine in particular in 2 1992, 1999 as fact evidence. 3 So are we to make our decision on 4 causality based on one study? I don't believe so. 5 We look at it in the package of all studies that 6 have been done because there are a lot of issues |
| 2 as to what those potential what potential 3 examples might be. 4 Q. Please turn over to the next path 5 The first full paragraph beginning 6 "In support of." 7 A. Yeah. | formation 1 the multiple studies mine in particular in 2 1992, 1999 as fact evidence. 3 So are we to make our decision on 4 causality based on one study? I don't believe so. 5 We look at it in the package of all studies that 6 have been done because there are a lot of issues 7 that could be at play as to why one study seems to |
| 2 as to what those potential what potential 3 examples might be. 4 Q. Please turn over to the next pa 5 The first full paragraph beginning 6 "In support of." 7 A. Yeah. 8 Q. You see that paragraph? | formation 1 the multiple studies mine in particular in 2 1992, 1999 as fact evidence. 3 So are we to make our decision on 4 causality based on one study? I don't believe so. 5 We look at it in the package of all studies that 6 have been done because there are a lot of issues 7 that could be at play as to why one study seems to 8 be somewhat different from another. |
| 2 as to what those potential what potential 3 examples might be. 4 Q. Please turn over to the next pa 5 The first full paragraph beginning 6 "In support of." 7 A. Yeah. 8 Q. You see that paragraph? 9 A. Yes. | formation 1 the multiple studies mine in particular in 2 1992, 1999 as fact evidence. 3 So are we to make our decision on 4 causality based on one study? I don't believe so. 5 We look at it in the package of all studies that 6 have been done because there are a lot of issues 7 that could be at play as to why one study seems to 8 be somewhat different from another. 9 Q. I'm finished with that study. |
| 2 as to what those potential what potential sexamples might be. 4 Q. Please turn over to the next part of the first full paragraph beginning the support of the second sentence says: 2 as to what those potential what potential sexamples might be. 4 Q. Please turn over to the next part of the second sentence says: | formation ial 1 the multiple studies mine in particular in 2 1992, 1999 as fact evidence. 3 So are we to make our decision on 4 causality based on one study? I don't believe so. 5 We look at it in the package of all studies that 6 have been done because there are a lot of issues 7 that could be at play as to why one study seems to 8 be somewhat different from another. 9 Q. I'm finished with that study. 10 A. Okay. |
| 2 as to what those potential what potential sexamples might be. 4 Q. Please turn over to the next part of the first full paragraph beginning the support of." 7 A. Yeah. 8 Q. You see that paragraph? 9 A. Yes. 10 Q. The second sentence says: 11 "However, a non-causal | formation 1 the multiple studies mine in particular in 2 1992, 1999 as fact evidence. 3 So are we to make our decision on 4 causality based on one study? I don't believe so. 5 We look at it in the package of all studies that 6 have been done because there are a lot of issues 7 that could be at play as to why one study seems to 8 be somewhat different from another. 9 Q. I'm finished with that study. 10 A. Okay. 11 MR. HEGARTY: The next study I |
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| Page 342 | Page 344 |
|---|---|
| 1 your expert report? | 1 A. Am I in the right study? Hold on. |
| 2 A. Yes. Uh-huh. | 2 Q. Terry. |
| 3 Q. This is a pooled study of | 3 A. Yeah, 819 is just graphs. Oh, no, |
| 4 case-control data; is that correct? | 4 819. Yes, I'm sorry. Yeah. Left-hand column. |
| 5 A. Yes. | 5 Yes. Sorry. |
| 6 Q. Please turn to page 820. | 6 Q. They note that with regard to |
| 7 A. Uh-huh. | 7 restricting their analysis to genital powder |
| 8 While you're getting that together, | 8 applications that occurred before tubal ligation |
| 9 could we go off the record? | 9 or hysterectomy made no substantive difference in |
| MR. HEGARTY: Yes, we can. | 10 the results, correct? |
| 11 (Recess: 4:07 p.m | 11 A. (Reviews document.) |
| 12 4:21 p.m.) | 12 "That occurred before tubal ligation |
| MR. HEGARTY: We are back on | 13 or hysterectomy made no substantive difference in |
| 14 the record. | 14 the results." |
| 15 BY MR. HEGARTY: | 15 And I'd like to see that data for |
| 16 Q. Doctor, I had asked you previously | 16 studies that collected data on timing. |
| 17 about presentations that you may have talked about | 17 This was if you'll excuse me, I |
| 18 talcum powder use and ovarian cancer. | 18 just wanted to make sure. |
| Did you look at your CV to see if | 19 Q. How long is that going to take you |
| 20 you found a presentation where that might have | 20 to look at that? |
| 21 come up? | 21 A. What? |
| 22 A. Yes. Yes, I did. | 22 Q. How long will it take you to look at |
| 23 Q. What did you find? | 23 that? |
| 24 A. In 1998 I believe. It was open a | 24 A. Not long but |
| Page 343 | Page 345 |
| 1 second ago. But 1998 at the Dana Farber Cancer | 1 (Reviews document.) |
| 2 Institute on the epidemiology of ovarian cancer. | 2 I'm sorry. I need to see where it |
| 3 Q. Was that the last time you discussed | 3 is. |
| 4 risk factors for ovarian cancer? | 4 (Reviews document.) |
| 5 A. Yes. | 5 I don't see it in the table. |
| 6 Q. That is in a public forum? | 6 Q. You need to look at it before you |
| 7 A. That's correct. | 7 can answer? |
| 8 Q. Do you recall if you talked about | 8 A. No, I can I can go ahead and |
| 9 talcum powder use and ovarian cancer at that | 9 answer. |
| 10 presentation? | They they yes, that's what |
| 11 A. I don't recall, but I'm sure that I | 11 they that's what they said. I don't know |
| 12 did because it was certainly one of them. | 12 whether or not they looked at that with respect to |
| 13 Yes, 1998, Dana Farber Cancer | 13 taking it into account, taking into account |
| 14 Institute. | 14 applications. So Table 3. |
| 15 Q. Please look at the Terry study and, | 15 (Reviews document.) |
| 16 rather than 820 where I directed you before, go to | 16 Q. Do you need longer to look at it? |
| 17 819 of that study. | 17 Let's go off the record. |
| 18 A. Uh-huh. | 18 A. Yeah, let's go off the record. That |
| 19 Q. Left-hand column, first paragraph. | 19 will be fine. I'm okay with that. I just want to |
| 20 MR. TISI: I can't find my | 20 make sure that |
| 21 copy of it. I apologize. | 21 MR. TISI: I'm actually not. |
| 22 THE WITNESS: 819? | 22 THE WITNESS: Sorry. |
| 23 BY MR. HEGARTY: | MR. TISI: I want you to stay |
| 24 Q. Page 819. | on the record. |

| | Page 346 | | Page 348 |
|----|---|----|---|
| 1 | MR. HEGARTY: We're off the | 1 | 1.32 in the highest in the highest level. |
| 2 | record. | 2 | Q. The authors, though, in the |
| 3 | MR. TISI: No, we're on the | 3 | "Abstract" make the statement on page 1 that: |
| 4 | record. | 4 | "Among genital powder users, we |
| 5 | MR. HEGARTY: No, we're off | 5 | observed no significant trend in risk with |
| 6 | the record. Chris, come on. We've | 6 | increasing number of lifetime applications." |
| 7 | always done this. If somebody needs more | 7 | Do you see where I'm reading? |
| 8 | time, we've always gone off the record. | 8 | A. On the "Abstract." |
| 9 | (Recess: 4:25 p.m | 9 | Q. Isn't that the same thing as saying |
| 10 | 4:26 p.m.) | 10 | 7 |
| 11 | MR. HEGARTY: We're back on | 11 | A. Well, they're again, they're |
| 12 | the record. | 12 | doing it based on statistical significance, and I |
| 13 | BY MR. HEGARTY: | 13 | disagree with that approach to make the |
| 14 | Q. I pointed you to the statement on no | | interpretation. |
| | difference in between in patients that had a tubal | | All of the confidence intervals are |
| | ligation or hysterectomy. | | relatively narrow. All of them are at 1.0 or |
| 17 | That's what they found; is that | | higher on the lower bound, and at the highest |
| | correct? | | quartile you see at minimum a 16 percent excessive |
| 19 | A. I'm sorry. Repeat the question. | | risk, which is very consistent from anywhere 16 |
| 20 | Q. The statement I read to you earlier | | percent to 52 percent, which is very consistent |
| | is an accurate statement, correct? | | with those who are the highest exposed component |
| 22 | A. Oh. That "Restricting our exposure | | of the population. |
| | to genital powder applications that occurred | 23 | Q. Please turn to page 19 of your |
| 24 | before tubal ligation or hysterectomy made no | 24 | report. |
| 1 | Page 347 | 1 | Page 349 |
| | substantive difference in the results"? | 1 | A. Page 19 of my report. |
| 2 | Q. Correct. | 2 | Q. In your section on biologic |
| 3 | That's a correct statement? | 3 | 1 |
| 4 | A. Well, that's what they report. | 4 | Do you see that section? A. I do. |
| 5 | Q. Did you make reference to that in your report or comment on that statement in your | 5 | |
| 6 | 5 | | Q. You cite at that part of your report |
| 8 | report? A. I don't believe I did. However, | 8 | a single study discussing talc and the ovaries of 2019, study by McDonald, correct? |
| | | 9 | A. Yes. |
| | there is some suggestion that talc use could be inhaled and have a deleterious effect in some | 10 | MR. HEGARTY: I'm going to |
| | women who are still applying it after after | 11 | mark that as an exhibit. |
| | closure of the genital tract. | 12 | Let's go off the record real |
| 13 | So I suppose there's there's | 13 | quick. |
| | possible explanations, but the findings are about | | (Recess: 4:30 p.m |
| | the same and positive in both situations, | 15 | 4:31 p.m.) |
| | according to the data. | | BY MR. HEGARTY: |
| 17 | Q. The Terry study also found no | 17 | Q. As I asked you just before we took a |
| | increasing trend with increasing dosage, correct? | | - |
| 19 | A. Actually, that's not true. | | report a single study by McDonald from 2019, |
| 20 | If you look at Table 5 and you look | | correct? |
| | at the lower confidence interval, it goes from 1.0 | | A. Yes, that's correct. |
| | up to 1.16 and the upper confidence interval | 22 | MR. HEGARTY: I'll mark that |
| | continues to go up as well. So in my view and | | study as our next exhibit, which is |
| | the rates go from 1.14 to 1.23, 1.22 ended up to | 24 | • |
| | | | |

Document 33295-64

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| | P. 250 | | D 072 |
|----|---|----|--|
| 1 | Page 350 (Document marked for | 1 | Page 352 MR. TISI: Do you mind me |
| 2 | identification as Harlow Exhibit 24.) | 2 | looking over? |
| 3 | THE WITNESS: Uh-huh. | 3 | MR. HEGARTY: No. Please. |
| 4 | BY MR. HEGARTY: | - | BY MR. HEGARTY: |
| 5 | Q. This is the study you rely upon for | 5 | Q. 598. |
| 6 | | 6 | A. Yeah. |
| 7 | | 7 | Q. In the bottom left-hand corner, it |
| 8 | A. It's one of the studies, yes. | | says: |
| 9 | Q. You state at the end of the | 9 | "Correlative SEM/EDX of the control |
| | paragraph when discussing McDonald, that is, the | | tissue blocks showed a total of four talc |
| | end of your first paragraph under Section 4 on | | particles across all patients: two in patient 2 |
| 1 | page 19 that with regard to the patients in the | | and two in patient 3." |
| | | 13 | Do you see where I'm reading? |
| | study and talc particles just tell me when you're there. | 14 | A. I do. |
| 15 | • | 15 | |
| 16 | , | _ | Q. That shows that the McDonald study found talc particles in two of the six control |
| - | Q. With regard to the control patients in the study that none was found and then that no | | patients, correct? |
| | talc was found | 18 | A. Yes. |
| 19 | Let me restate that. | 19 | Q. So the statement that you made on |
| 20 | A. Yeah. | | paragraph 19 under Section 4 that "None was found |
| 21 | | | in the negative exposure controls" is not |
| | | | accurate, correct? |
| | the first paragraph under Section 4, you make the statement that "None" meaning none, no talc | 23 | A. (Reviews document.) |
| 1 | particles "were found in the negative exposure | 24 | Q. How much time do you need to review |
| 24 | | 24 | - |
| 1 | Page 351 controls," correct? | 1 | Page 353 the paper, Doctor? |
| 2 | A. That's correct. | 2 | A. (Reads document.) |
| 3 | Q. That's not a true statement, is it? | 3 | I must have I must have |
| 4 | A. Well, unless I misread it. I'm | - | misquoted. |
| 5 | happy to re-look at that. | 5 | Q. So the McDonald paper actually shows |
| 6 | | | a finding of talc particles in women who had never |
| 7 | | l | reported using talcum powder in their ovaries, |
| 8 | - · | l | correct? |
| 9 | , , , | 9 | A. (Reviews document.) |
| 10 | | 10 | |
| 11 | THE WITNESS: Page 598. | 11 | A. (Reviews document.) |
| 12 | MR. TISI: That's his. I'm | 12 | Q. How much time do you need to review |
| 13 | sorry. Did you give him a copy? | | the document? |
| 14 | | 14 | A. Just a second, please. |
| 15 | , , | 15 | (Reviews document.) |
| 16 | | 16 | Well, it appears that they were |
| 17 | MR. HEGARTY: I gave you two | l | found in in both. Those with and without talc |
| 18 | copies. | l | or those with and without exposure to perineal |
| 19 | - | l | exposure to talc. |
| 20 | · · · · · · · · · · · · · · · · · · · | 20 | Q. If studies like this do show talc in |
| 21 | right. | | the ovaries of women who had never used talcum |
| 22 | MR. HEGARTY: I handed over | | powder, does that go against a clear finding of |
| 23 | two copies. | | biologic plausibility between talcum powder use |
| 24 | - | | and ovarian cancer? |
| ∠+ | | | |

| | Page 354 | | Page 356 |
|---------------|--|----|--|
| 1 | A. I don't think so. Not necessarily. | 1 | not said "none," and I appreciate you |
| 1 | Particularly given that | 2 | giving me a chance to take a look more |
| 3 | (Reviews document.) | 3 | closely at the article. |
| 4 | Particularly given the fact that | 4 | There was talc found in two of |
| 1 | women who have actually applied it to the genital | 5 | the six controls, but those two had |
| | area have applied it, and those who I believe to | 6 | undergone pelvic surgery 30 years before, |
| | be at increased risk have applied it regularly, | 7 | and the authors suggest that the talc on |
| | and there have been there's substantial | 8 | the surgical gloves could have been |
| 1 | evidence to suggest that the talc has some | 9 | responsible for that. |
| | asbestiform, asbestos contamination. | 10 | And they specifically say that |
| | · | 11 | the six control cases supported the |
| 11 | (Reviews document.) | 12 | |
| 12 | Q. Are you finished with your answer? | | contention that talc is rarely found in |
| 13 | A. I am. I am. I'm just checking to | 13 | surgically resected pelvic tissues from |
| | make sure that this is, in fact, the article that | 14 | patients with no prior perineal or body |
| | I cited. | 15 | use exposure. |
| 16 | I'm done with mine. | 16 | The four talc particles found |
| 17 | Q. Okay. We haven't agreed upon a lot | 17 | by the SEM/EDX were in only two patients, |
| | today, Dr. Harlow. | 18 | both of whom had undergone pelvic surgery |
| 19 | A. Yeah. | 19 | procedures more than 30 years ago. And |
| 20 | Q. But you do agree that your statement | 20 | given that history and timeline, the talc |
| | with regard to the McDonald study that "None was | 21 | could have been introduced from the |
| | found in the negative exposure controls" is | 22 | ambient environment. |
| 1 | incorrect? | 23 | So I agree that I misspoke |
| 24 | MR. TISI: Objection. If you | 24 | when I said none of the controls, but |
| 1 | Page 355 | 1 | Page 357 |
| $\frac{1}{2}$ | need time to review the paper, feel free | 1 | clearly this would not provide evidence |
| 2 | to go off the record and we can do that. THE WITNESS: I would like to | 2 | against the biological plausibility. |
| 3 | | | BY MR. HEGARTY: |
| 4 | go off the record. It's going to | 4 | Q. At the end of this section on |
| 5 | MR. HEGARTY: Okay. Let's go | | biologic plausibility in your report I'm |
| 6 | off the record. Sure. | _ | looking at the bottom of page 19. |
| 7 | THE WITNESS: take another | 7 | A. Uh-huh. |
| 8 | short look. | 8 | Q. You make the statement that: |
| 9 | (Recess: 4:37 p.m | 9 | "Although the exact mechanism |
| 10 | 4:44 p.m.) | | exact pathogenic mechanism by which talc may incur |
| 11 | MR. HEGARTY: We are back on | | carcinogenesis is unknown, plausible mechanisms |
| 12 | the record. | | may involve inflammation." |
| 13 | | 13 | Do you see where I'm reading? |
| 14 | Q. We took a break. | 14 | A. I do. |
| 15 | Doctor, I commented that you and I | 15 | Q. You don't cite in this part of your |
| l | have not agreed on a lot of things here today, but | | |
| 17 | ē : | | |
| | found in the negative exposure controls" in | | inflammation, correct? |
| 1 | reference to the McDonald 2019 study is an | 19 | A. Well, in my in my review of talc |
| | inaccurate statement? | | of the association in the 1994 review article, we |
| 21 | MR. TISI: Objection. | | do talk about inflammation, and there are a number |
| 22 | THE WITNESS: Yeah. I think | | of of articles that have suggested that |
| 23 | it's important to point out. | | inflammation is a plausible mechanism by which |
| 24 | I probably I should have | 24 | talc could induce ovarian cancer, particularly |

| Page 358 1 when talc is embedded in the in the inclusion | Page 360 |
|---|--|
| 2 cysts after ovulation and basically remain there | 1 body of your report any studies that talk about 2 tale and inflammation? |
| 3 and lead to an inflammatory process. | 3 A. I have not, but I have done so in my |
| 4 Q. Listen to my question, though, | 4 previous report, as I said before your discussion |
| 5 Doctor. | 5 with counsel here. |
| 6 In the body of your report for this | 6 Q. As part of your work in preparing |
| 7 case, you don't cite to any studies that comment | 7 your report, did you do a comprehensive medica |
| 8 on talc and inflammation, correct? | 8 literature search with regard to inflammation and |
| 9 MR. TISI: Objection. | 9 ovarian cancer? |
| 10 Misstates. He says he relies on his own | 10 A. No, I didn't. Again, I didn't need |
| 11 studies. | 11 to do that in order to come to the conclusion that |
| MR. HEGARTY: Please, don't | 12 there was a biologically plausible mechanism by |
| 13 answer for him, Chris. | 13 which ovarian by which talc could influence |
| 14 MR. TISI: No, I'm not | 14 ovarian cancer. |
| answering for him. | 15 Q. Is it your opinion in this case that |
| MR. HEGARTY: Come on. It's | 16 inflammation is the cause of ovarian cancer? |
| 17 not a proper objection and you know it. | MR. TISI: Objection. |
| MR. TISI: It is. It is | 18 THE WITNESS: I I cannot |
| because it's misleading. | state any one particular pathogenic |
| 20 BY MR. HEGARTY: | 20 mechanism is responsible for the path |
| 21 Q. You can answer, Doctor. | for the carcinogenic process. There are |
| MR. TISI: To the extent you | several that have been proposed. |
| rely on your prior studies, which are | 23 BY MR. HEGARTY: |
| 24 clearly outlined in your report, you | Q. Please turn to page 19 of your |
| Page 359 | Page 361 |
| 1 clearly incorporate, you're entitled to | 1 report, if you're not there already. |
| 2 that. Word piece is not appropriate. | 2 A. I am there. |
| 3 MR. HEGARTY: Chris, I think | 3 Q. In the upper part of that page of |
| 4 I'm going we're going to have an issue | 4 your report, you make reference to a statement by |
| 5 with the judge. We'll just swear you in. | 5 the American Statistical Association, correct? |
| 6 You just gave him an answer to give back | 6 A. Yes. |
| 7 to me. | 7 Q. And that statement you make is in |
| 8 MR. TISI: No, I didn't. | 8 support of the statements you make in that |
| 9 MR. HEGARTY: Yes, you did. | 9 paragraph that: |
| MR. TISI: It's so unfair what | 10 "A consensus is slowly building |
| 11 you're doing. | 11 among scientists that statistical significant |
| MR. HEGARTY: Well | 12 testing has been a source of many errors in |
| MR. TISI: When he says | 13 interpretation, and should be avoided." |
| when he says he | 14 Correct? |
| MR. HEGARTY: we'll let the | 15 A. That's correct. |
| judge decide if that was unfair. | MR. HEGARTY: I'm going to |
| MR. TISI: When he says | mark as our next exhibit, Exhibit 25, a |
| when he says he incorporates by reference | document entitled "ASA President's Task |
| his own studies and his own studies | 19 Force Statement on Statistical |
| 20 discuss it. | 20 Significance and Replicability." |
| MR. HEGARTY: We're not going | (Document marked for |
| to reach an agreement on this. | 22 identification as Harlow Exhibit 25.) |
| 23 BY MR. HEGARTY: | 23 BY MR. HEGARTY: |
| Q. Doctor, do you cite anywhere in the | Q. Please excuse the highlighting. |

| Page 362 | Page 36- |
|--|---|
| 1 They copied my highlighting when they weren't | 1 statistical inference that may be useful to the |
| 2 supposed to. | 2 scientific community." |
| 3 A. Uh-huh. | 3 Did I read that correctly? |
| 4 Q. Have you read this before right now? | 4 A. Yes, you did. |
| 5 A. I don't believe I have since this | 5 Q. Do you disagree with that last |
| 6 was not in the scientific literature, and my | 6 statement that I just read? |
| 7 reference is by Amrhein, Greenland, and McShane. | 7 A. I've never disagreed that p-values |
| 8 Q. I'm talking about the reference you | 8 are not a tool in determining in determining a |
| 9 make on page 19 | 9 strength of an association, but you don't need a |
| 10 A. I understand. | 10 p-value. You can look at the confidence intervals |
| 11 Q of the American Statistical | 11 to determine whether or not the confidence |
| 12 Association. | 12 interval includes or doesn't include 1.0 and, by |
| 13 A. I understand, and it comes from | 13 definition, that is essentially showing what the |
| 14 oh. It is it is a quote that was stated in the | 14 p-value might be. |
| 15 article by Amrhein. | 15 Q. Please look at the very last |
| One recent commentary in "Nature" | 16 sentence on page 1. |
| 17 and endorsed by 800 signatories stated this. | 17 A. Yes. |
| Oh, and then you're talking about | 18 Q. It reads: |
| 19 the consensus statement from the American | 19 "P-values are valid statistical |
| 20 Statistical Association above. | 20 measures that provide convenient conventions for |
| Q. Right. That's what I'm referring | 21 communicating the uncertainty inherited |
| 22 to. | 22 inherent in quantitative results. Indeed, |
| 23 A. "A p-value, or statistical | 23 p-values and significance tests are among the most |
| 24 significance, does not measure." Yes. | 24 studied and best understood statistical procedures |
| Page 363 | Page 36: |
| 1 Q. Please look at Exhibit Number 25. | 1 in the statistics literature." |
| 2 A. I'm looking. | 2 Do you agree with those two |
| 3 Q. It says in the first full | 3 statements? |
| 4 paragraph | 4 A. Sure. |
| 5 A. On what page? | 5 Q. Carrying on in that paragraph, it |
| 6 Q. First paragraph. | 6 goes on to say: |
| 7 A. Yes. | 7 "They are important tools that have |
| 8 Q. First page. | 8 advanced science through their proper |
| 9 A. Yes. | 9 application." |
| 10 Q. Second sentence. | Do you agree with that statement? |
| "In 2019, the president of the | 11 A. "Through their proper application," |
| 12 American Statistical Association established a | 12 yes. |
| 13 task force to address concerns a 2019 editorial in | Q. Please look at the very last line in |
| 14 'The American Statistician' (an ASA journal) might | 14 the middle of that page that begins "In summary." |
| 15 be mistakenly interpreted as official ASA policy. | MR. TISI: Feel free to take a |
| 16 (The editorial recommended eliminating the use of | look at the document. |
| 10 (The editorial recommended eliminating the use of | 17 THE WITNESS: Yeah. I'm just |
| 17 'p less than .05' and 'statistically significant' | |
| | not seeing where it says "In summary." |
| 17 'p less than .05' and 'statistically significant' | 3 |
| 17 'p less than .05' and 'statistically significant' 18 in statistical analysis.) This document is the 19 statement of the task force, and the ASA invited | 18 not seeing where it says "In summary."19 BY MR. HEGARTY: |
| 17 'p less than .05' and 'statistically significant' 18 in statistical analysis.) This document is the 19 statement of the task force, and the ASA invited 20 us to publicize it. Its purpose is two-fold: to | 18 not seeing where it says "In summary." 19 BY MR. HEGARTY: 20 Q. Right in the middle. Right there. |
| 17 'p less than .05' and 'statistically significant' 18 in statistical analysis.) This document is the 19 statement of the task force, and the ASA invited 20 us to publicize it. Its purpose is two-fold: to 21 clarify that the use of p-values and significance | 18 not seeing where it says "In summary." 19 BY MR. HEGARTY: 20 Q. Right in the middle. Right there. 21 MR. TISI: I know, but feel |
| 17 'p less than .05' and 'statistically significant' 18 in statistical analysis.) This document is the 19 statement of the task force, and the ASA invited 20 us to publicize it. Its purpose is two-fold: to | 18 not seeing where it says "In summary." 19 BY MR. HEGARTY: 20 Q. Right in the middle. Right there. 21 MR. TISI: I know, but feel |

| Proc 200 | D 200 |
|---|--|
| Page 366 | Page 368 1 in front of me. But probably like 0.8 or 0.9 to |
| 2 MR. TISI: If you have not | 2 about 1.3 or 1.4. |
| 3 seen this recently, please take a look at | 3 If you assume that that is an |
| 4 it. | 4 attenuation of the true effect and that the |
| 5 BY MR. HEGARTY: | 5 multiple, multiple case-control studies have all |
| 6 Q. It reads: | 6 shown an association of about 1.3, to me that |
| 7 "In summary, p-values and | 7 seems fairly comparable. |
| 8 significance tests, when properly applied and | 8 So that's the way I would interpret |
| 9 interpreted, increase the rigor of the conclusions | 9 it, and that's the way both Dr. Rothman and I |
| 10 drawn from data. Analyzing data and summarizing | 10 interpreted that, and we tried to explain that |
| 11 results are often more complex than is sometimes | 11 rationale. |
| 12 popularly conveyed. Although all scientific | Q. We talked somewhat today about the |
| 13 methods have limitations, the proper application | 13 O'Brien 2020 study, and you talk about it in you |
| 14 of statistical methods is essential for | 14 expert report, correct? |
| 15 interpreting the results of data analyses and | 15 A. That's correct. |
| 16 enhancing the replicability of scientific | MR. HEGARTY: I've marked as |
| 17 results." | Exhibit Number 26 the 2020 O'Brien study. |
| Do you agree with all those | 18 (Document marked for |
| 19 statements? | 19 identification as Harlow Exhibit 26.) |
| 20 A. I do, but that does not talk about | 20 THE WITNESS: Yes. |
| 21 the use of statistical significance for making | 21 BY MR. HEGARTY: |
| 22 inferences about causation. It is one of many | 22 Q. You have read that study; is that |
| 23 tools that we use to assess the precision of risk | 23 correct? |
| 24 estimates. | A. Not only have I read it, I've |
| Page 367 | Page 369 |
| 1 Q. You make the statement in your | 1 written a letter to the editor. |
| 2 report that you found that there is reasonable | 2 Q. Which we'll talk about as well here |
| 3 consistency between case-control and cohort | 3 in a moment. |
| 4 studies. | 4 Please turn over to page 56 of this |
| 5 What did you mean by "reasonable | 5 paper. Under the "Discussion" section. |
| 6 consistency"? | 6 A. Uh-huh. |
| 7 A. Under the assumption that based on | 7 Q. The very first line reads: |
| 8 the limitations of the cohort study in terms of | 8 "In this pooled of analysis of 4 |
| 9 the way in which they assessed exposure, we can | 9 large U.S. cohorts, there was no statistically |
| 10 expect that those overall risk estimates are | 10 significant association between self-reported use |
| 11 attenuated because of that. | 11 of powder in the genital area and risk of ovarian |
| Thus, given that there is an | 12 cancer." |
| 13 attenuation of the cohort study estimates in the | That's a correct statement, true? |
| 14 one cohort study I believe to be the best in terms | 14 A. Well, I believe that I took issue |
| 15 of approximating the true risk, which is the | 15 with that particular statement because other |
| 16 Nurses' Health Study, I see that I see that the | 16 findings in this particular paper showed a |
| 17 association on all not all that different. | 17 different association in those with patent genital |
| 18 Even if you take the likely | 18 tracts. |
| 19 attenuated association of 1.09, which you continue | 19 Q. The next line says: |
| 20 to refer to as the overall association, even | 20 "There were no clear dose-response |
| 21 though in further analyses in that paper it's | 21 transfer for duration and frequency of powder use |
| 22 substantially higher, it's not unreasonable and | 22 in the genital area in relation to ovarian cancer 23 risk." |
| 23 you look at the confidence interval that's | |
| 24 probably around I don't know. I don't have it | Those are those are also true |

| Page 370 | | Page 372 |
|--|----------------------------|---|
| 1 statements, correct? | 1 | a patent open genital tract are going to be at |
| 2 A. Those that's what they said, but, | 1 | lower risk if not null risk for for this |
| 3 again, as I pointed out in the report and even in | 1 | association. |
| 4 my letter to the editor, exposure assessment in | 4 | Q. Dr. Harlow, statistically, there was |
| 5 two of these three I mean, really all of them, | 5 | • |
| 6 but particularly in two of the three were not | 6 | without patent tubes, correct? |
| 7 were were incomplete in terms of being able | 7 | MR. TISI: Objection. Asked |
| 8 to truly obtain the kind of exposure assessment | 8 | and answered. |
| 9 that we're actually able to do in case-control | 9 | THE WITNESS: Well, no. I'm |
| 10 studies. | 10 | |
| | 11 | sorry. MR. TISI: You got to let me |
| 11 And the issue well, I'll just | 12 | _ |
| 12 stop there. Go ahead and ask another question. | 13 | object. |
| 13 Q. As you mentioned just a moment ago, | | THE WITNESS: Sorry. |
| 14 you do make reference to the study's findings with | 14 | MR. TISI: Objection. Asked |
| 15 regard to the data as to women with patent genital | 15 | and answered. |
| 16 tracts, correct? | 16 | You may answer. |
| 17 A. Yes. | 17 | THE WITNESS: Sorry. |
| 18 Q. As the authors note, though | 18 | MR. TISI: No, that's okay. |
| 19 A. Uh-huh. | 19 | THE WITNESS: Just because |
| Q they found no statistical | 20 | there the difference between 1.0 1.0 |
| 21 difference between in the data between women | 21 | with a confidence interval with a with |
| 22 with patent tubes and women who did not have | 22 | a confidence interval of .86 to 1.15, |
| 23 patent tubes, correct? | 23 | which is almost directly, directly, |
| And where do they specifically say | 24 | estimated as null with a hazard of 0.99, |
| Page 371 | | Page 373 |
| 1 that? | 1 | to have to say that that is statistically |
| 2 Q. Please look at the abstract. | 2 | different from a hazard ratio of 1.13 |
| 3 A. Well, I'm looking at on page 54 | 3 | with a confidence interval of 1.01 to |
| 4 where they say in the second column: | 4 | 1.26 would does it make sense to then |
| 5 "When restricted to women with | 5 | say, oh, because they're not |
| 6 patent reproductive tracts at baseline, the hazard | 6 | statistically different, then we don't |
| 7 ratio was 1.13 and the estimated | 7 | believe then we should just ignore |
| 8 covariate-adjusted risk difference was 0.15. | 8 | that association that we see in women |
| 9 Among women without patent reproductive tracts, | 9 | with patent genital tracts. |
| 10 the estimated hazard ratio was 0.99." | 10 | It is ludicrous to apply a |
| 11 Q. Then they go on to say: | 11 | statistical test in this situation to |
| 12 "And the P value for heterogeneity | 12 | diminish or ignore an association, in my |
| 13 comparing the results for women with patency | 13 | view. |
| 14 versus without was .15." | 14 | MR. HEGARTY: Let me show you |
| 15 Correct? | 15 | what I've marked as Exhibit Number 27. |
| | | (Document marked for |
| 16 A. That's what they say, but one | 16 | • |
| 16 A. That's what they say, but one 17 doesn't need to do a statistical test of | 17 | identification as Harlow Exhibit 27.) |
| | 17 18 | identification as Harlow Exhibit 27.) BY MR. HEGARTY: |
| 17 doesn't need to do a statistical test of | 17 | identification as Harlow Exhibit 27.) |
| 17 doesn't need to do a statistical test of 18 differences to recognize that the association | 17 18 | identification as Harlow Exhibit 27.) BY MR. HEGARTY: |
| 17 doesn't need to do a statistical test of 18 differences to recognize that the association 19 seems to be much strongly observed in those with a | 17 18 19 | identification as Harlow Exhibit 27.) BY MR. HEGARTY: Q. Exhibit Number 27 is an editorial |
| 17 doesn't need to do a statistical test of 18 differences to recognize that the association 19 seems to be much strongly observed in those with a 20 patent patent tract. | 17 18 19 20 | identification as Harlow Exhibit 27.) BY MR. HEGARTY: Q. Exhibit Number 27 is an editorial A. Yes. |
| 17 doesn't need to do a statistical test of 18 differences to recognize that the association 19 seems to be much strongly observed in those with a 20 patent patent tract. 21 And as I believe Dr. Rothman and | 17 18 19 20 21 | identification as Harlow Exhibit 27.) BY MR. HEGARTY: Q. Exhibit Number 27 is an editorial A. Yes. Q that was written |

| Page 374 | Page 376 |
|--|--|
| 1 Have you read this before today? | 1 Q. She's talking about you, right? |
| 2 A. I have. | 2 MR. TISI: Objection. Come |
| 3 Q. Do you know either of these two | 3 on. |
| 4 doctors? | 4 THE WITNESS: What do you |
| 5 A. I don't know them. | 5 mean she's talking about me? |
| 6 Q. Please turn over to page 30. | 6 BY MR. HEGARTY: |
| 7 A. Uh-huh. | 7 Q. Well, she |
| 8 Q. Towards the bottom of the left-hand | 8 MR. TISI: Are you suggesting |
| 9 column. | 9 with all his background? Honestly, that |
| 10 A. Uh-huh. | 10 is insulting. |
| 11 Q. Beginning with "The fact that." | MR. HEGARTY: Please. Please. |
| Do you see where I'm reading? | MR. TISI: Do not insult my |
| 13 A. Is it in the left-hand column? | 13 witness ever. |
| 14 Q. Left-hand column. | 14 MR. HEGARTY: Please. Chris, |
| 15 A. Hold on. | 15 Make an objection. Make an objection. |
| 16 Q. Right here. Very bottom paragraph. | 16 MR. TISI: You are suggesting |
| 17 A. In fact. | he's epidemiologically unsophisticated? |
| 18 Q. "The fact that." That's the | 18 That's beneath you. |
| 19 beginning of the sentence. | 19 MR. HEGARTY: I asked if she |
| 20 A. Oh, got it. Thank you. | was talking about you. |
| 21 Q. It reads: | 21 MR. TISI: Oh, you think so? |
| 22 "The fact that there was there | 22 BY MR. HEGARTY: |
| 23 are no significant differences in the HRs in the | 23 Q. You can answer. |
| 24 patent (HR, 1.13 [95% confidence interval, 1.01 to | 24 A. Well, first of all |
| | , |
| Page 375 1 1.26]) and nonpatent subgroups (HR, .99 [95% | Page 377 MR. TISI: Ask her about the |
| 2 confidence interval, 0.86 to 1.15]; P value for | 2 statement. |
| 3 heterogeneity comparing these subgroups of .15) | 3 BY MR. HEGARTY: |
| 4 confirms the overall conclusion that there is no | 4 Q. You can answer the question. |
| 5 demonstrable statistically significant association | 5 MR. TISI: Ask her about |
| 6 between use of powder in the genital area and | 6 ask him about the statement. |
| 7 ovarian cancer risk." | 7 MR. HEGARTY: Are you |
| 8 First of all, did I read that | 8 instructing him not to answer my |
| 9 correctly? | 9 question? |
| 10 A. You read what was written there, | 10 MR. TISI: I'm telling you to |
| 11 yes, correctly. | 11 ask a nonridiculous question. |
| 12 Q. Carrying over to the next paragraph | 12 MR. HEGARTY: I'm not going to |
| 13 from the bottom. | listen to what you tell me, Chris. |
| 14 A. Yeah. | 14 Please be quiet and let him answer the |
| 15 Q. "The subgroup analysis suggesting | 15 question. |
| 16 that women with intact reproductive tracts who | 16 MR. TISI: Don't ever do that |
| 17 used powder in the perineal area developed ovarian | to one of my witnesses again. |
| 18 cancer more frequently than nonusers is below the | 18 MR. HEGARTY: I'm not |
| 19 effect size that epidemiologists generally | 19 listening to you what you say. My |
| 20 consider important and should not be selectively | 20 question is appropriate. |
| 21 highlighted by the statistically unsophisticated | 21 MR. TISI: You better listen. |
| 22 reader as evidence of a relationship." | 22 BY MR. HEGARTY: |
| 23 Did I read that correctly? | 23 Q. Was that statement talking about |
| 24 A. You did read it correctly. | 24 your what you just told me about why you reject |
| 21 11. Tou did read it correctly. | 2. Jour what you just told life about willy you reject |

| PagelD. 200 | 701 | |
|---|--|--|
| D 270 | | D 200 |
| - 1 | 1 | Who is the primary, if there was |
| | _ | one, author of this document, of this letter to |
| | | the editor? |
| · · · · · · · · · · · · · · · · · · · | | A. Well, I was the first author, but I |
| • | | it was a somebody had to be first. It was a |
| • | | collaboration between the three of us. |
| | • | I was the one who initiated this |
| • | , | collaboration in response to this. |
| · · · · · · · · · · · · · · · · · · · | | Q. At the time that you wrote this |
| • | | letter to the editor |
| - | | A. Yes. |
| - | | Q you had been serving as a |
| | | consultant to plaintiffs' lawyers in cases |
| • | | involving talcum powder use and ovarian cancer |
| | | correct? |
| | | MR. TISI: Objection. |
| • • | | THE WITNESS: No, that's not |
| | | true. |
| • | | I told you, I believe, earlier |
| | | that I had stopped doing that as of 2017. |
| · · | | This was written in 2020. |
| | | BY MR. HEGARTY: |
| - | 23 | Q. Please look at the conflict of |
| | 24 | interest disclosure |
| Page 379 | | Page 381 |
| So I'm sorry. That's that's an | 1 | A. Yes. |
| inappropriate inappropriate comment. | 2 | Q in this document. |
| MR. HEGARTY: You mentioned | 3 | A. Yes. |
| your commentary and I marked your | 4 | Q. It reads: |
| commentary as Exhibit Number 28. | 5 | "Dr. Harlow reported publishing |
| (Document marked for | 6 | research and serving as a consultant on the topic |
| identification as Harlow Exhibit 28.) | 7 | of talc and ovarian cancer risk." |
| THE WITNESS: My letter to | 8 | Did I read that correctly? |
| | _ | |
| the editor? | 9 | A. That's correct, but I was not at the |
| the editor? BY MR. HEGARTY: Q. Sorry. I misspoke. | 10 | A. That's correct, but I was not at the time serving as a consultant. I was I was doing the appropriate thing and letting the |
| | statistical significance between the patent and nonpatent groups in this study? A. First of all, they couldn't be talking about me because I wrote my letter to the editor about this after this commentary had been written. So I don't know how they could possible be directing this comment to me. Q. Okay. Is this not addressing the issue you and I have been talking about about statistical significance between the patent and nonpatent tubes to patients? A. It is, and I don't know who this person is, but I don't see that they have a doctoral degree in epidemiology. And I don't believe that that kind that to me is what the American Statistical Association was saying in terms of inappropriately using statistical significance to make clinically relevant decisions. So in my field, we would not make that kind of a statement that would, in my view, minimize a potential risk of something that has been shown to possibly impact 10 percent of the incidence of ovarian cancer. Page 379 So I'm sorry. That's that's an inappropriate inappropriate comment. MR. HEGARTY: You mentioned your commentary and I marked your commentary as Exhibit Number 28. (Document marked for identification as Harlow Exhibit 28.) | statistical significance between the patent and nonpatent groups in this study? A. First of all, they couldn't be talking about me because I wrote my letter to the editor about this after this commentary had been written. So I don't know how they could possibly 6 be directing this comment to me. Q. Okay. Is this not addressing the issue you and I have been talking about about statistical significance between the patent and nonpatent tubes to patients? A. It is, and I don't know who this person is, but I don't see that they have a doctoral degree in epidemiology. And I don't believe that that kind that to me is what the American Statistical Association was saying in terms of inappropriately using statistical significance to make clinically relevant decisions. So in my field, we would not make that kind of a statement that would, in my view, minimize a potential risk of something that has been shown to possibly impact 10 percent of the incidence of ovarian cancer. Page 379 So I'm sorry. That's that's an inappropriate inappropriate comment. MR. HEGARTY: You mentioned your commentary and I marked your commentary as Exhibit Number 28. (Document marked for identification as Harlow Exhibit 28.) |

12 A. No worries.

13 Q. Your letter to the editor, which

14 happens to be under the "Comment & Response" 14 to the editor.

15 section, correct?

16 A. Yes.

17 Q. With regard to the letter to the

18 editor that we're looking at in Exhibit 28 --

19 A. Yes.

Q. -- your letter to the editor begins

21 over on page 2096, correct?

A. Yes, that's correct.

Q. The letter to the editor is from

24 three authors.

20 letting the readership know that I had received

16 refer back to the consulting you and I talked

12 readership know that I had been a consultant at

13 some point, but I was not when I wrote this letter

17 about with regard to the Chakalos case and other

Was your intent by that statement to

My intent was to be forthcoming in

21 some consulting arrangements in the past around

22 this.

18 cases?

15

19

Q.

23 Q. You did not report to the reader on 24 whose side you had consulted --

96 (Pages 378 - 381)

| Page 382 | Page 384 |
|---|--|
| 1 A. I did | 1 consultant with regard to talc and ovarian cancer? |
| 2 Q with regard to talc and ovarian | 2 MR. TISI: Objection. Asked |
| 3 cancer, correct? | 3 and answered. |
| 4 A. I did not. | 4 THE WITNESS: I didn't feel |
| 5 Q. Do you think it's important let | 5 it had any influence or bearing on my |
| 6 me ask a different way. | 6 on my conclusions here and, as I just |
| 7 Do you not think it's important for | 7 indicated before, this is a joint letter |
| 8 the reader to know whether you had been a | 8 between the three of us. And even if I |
| 9 consultant for plaintiffs' lawyers who are | 9 was trying to bias in one direction, it |
| 10 bringing lawsuits involving talcum powder use | would never have been approved by my |
| 11 versus Johnson & Johnson who's defending lawsuits | 11 coauthors. |
| 12 involving talcum powder use? | 12 BY MR. HEGARTY: |
| 13 A. I was not an expert. I was not | 13 Q. If you were to write this letter |
| 14 doing any expert testimony. | 14 today, would you identify in your conflict of |
| 15 I was merely being a consultant and | 15 interest disclosure that you're a |
| 16 evaluating scientific literature. It had no | 16 consultant/expert testifying for plaintiffs in |
| 17 bearing on my interpretation. | 17 cases involving talcum powder use and ovarian |
| 18 And all three of my coauthors and I | 18 cancer? |
| 19 have again, I had no idea what Dr. Rothman had | 19 MR. TISI: Objection. |
| 20 or had not done. When I wrote this, I did not | 20 THE WITNESS: May I answer |
| 21 know about his report in 2000. And to my | 21 the question? |
| 22 knowledge, Dr. Murray has not been involved in any | 22 MR. TISI: Sure. |
| 23 of this. | 23 THE WITNESS: Yes, I would. |
| This was a collaborative letter that | 24 Yes, I would. I'm not sure I would be |
| | · |
| Page 383 | Page 385 |
| 1 we wrote, and I could never have influenced my | 1 comfortable in a position doing that |
| 2 colleagues one way or another because of any kind | 2 simply because of the situation that I'm |
| 3 of past consulting that I've done. | 3 in right now. |
| 4 Q. You don't disclose a prior | 4 BY MR. HEGARTY: |
| 5 relationship in a conflict of interest disclosure | 5 Q. Please look at Drs. O'Brien, |
| 6 only if you believe it is biasing your statements | 6 Sandler, and Wentzensen's response letter at the |
| 7 or your opinions that you are writing, correct? | 7 bottom of page 2096 to 2097. |
| 8 MR. TISI: Objection. | 8 You've read that before today, |
| 9 THE WITNESS: I'm sorry. Can | 9 correct? |
| 10 you repeat that question? | 10 A. Oh. Oh, Dr. O'Brien's response. |
| 11 BY MR. HEGARTY: | 11 Q. Yes, or reply. |
| 12 Q. Sure. | 12 A. Yes. Yes, yes, yes. I'm sorry. |
| You don't only identify a conflict | 13 Yes. Uh-huh. |
| 14 of interest when you believe you are presenting | 14 Q. Please look at the bottom of page |
| 15 biased statements in a publication, correct? | 15 2096 in the right-hand column, second paragraph. |
| 16 A. I anytime I would be would | Dr. O'Brien and her coauthors write: |
| 17 write anything around the talc and ovarian cancer | 17 "Conversely, empirical evidence |
| 18 beyond what I had already published, knowing that | 18 supports that recall bias is present in |
| 19 I had spent a period of time as a consultant, it | 19 retrospective studies." |
| 20 would have been inappropriate for me not to have | That's what Dr. O'Brien wrote, |
| 21 indicated that disclosure, and so that's what I | 21 correct? |
| 22 did here. | 22 A. This was, again, not in response to |
| Q. Don't you think the reader was | 23 my letter. This was in response to Dr. Cramer's |
| 24 entitled to know on whose side you had been a | 24 letter. |

3

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1 Q. But without regard to who she's 2 responding to, that's what she wrote, correct?

A. She did write that.

But as you note in my report, there
are a number of -- of citations where I indicated
that recall bias has minimal to little impact on
estimates.

- 8 Q. So you disagree with that statement?
- 9 A. I don't disagree that there can be 10 recall bias in retrospective studies. I believe
- 11 I've been very clear that recall bias in those who
- 12 are at the highest level of exposure is unlikely
- 13 to explain the associations that we've observed.
 14 Q. The next statement by Dr. O'Brien

15 and others says:

16 "While true never users are unlikely 16 17 to report daily use, some users may fail to report 17

- 18 use and others may misreport frequency and
- 19 duration of use or type of product used. If
- 20 misclassification is differential by case status,
- 21 it could influence effect estimates in
- 22 case-control studies."
- Do you agree with those statements?
- A. Yes, but it could influence in

1 intact reproductive tracts, should not be

- 2 discounted because of lack of statistical
- 3 significance. For all estimates we reported 95
- 4 percent confidence intervals.
- 5 So do I believe that this is
- 6 important addition to the literature? Yes, I
- 7 absolutely do, when considering the limitations
- 8 related to these cohort studies.
- 9 I'm not suggesting this is not an
- 10 important contribution. I'm suggesting that, in
- 11 our view, given the attenuation that is likely to
- 12 be occurring for many of the reasons that we
- 13 report in the letter, that we report in our
- 14 report, make this an important contribution and to
- 15 me validates the consistency of the findings that
- 16 we see in case-control studies.
- 7 Q. Dr. O'Brien in her reply doesn't
- 18 retract or withdraw the 2020 O'Brien paper or any
- 19 statements in it, correct?
- 20 A. No. She merely agrees with our
- 21 interpretation.
- Q. She agrees with what she says she
- 23 agrees with in her reply, correct?
- A. That's right, but I believe there's

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1 either direction. It doesn't necessarily

- 2 influence in one direction or the other.
- Q. Please look at the very last
- 4 paragraph on the next page of Dr. O'Brien and
- 5 others' response. Please tell me when you can --
- 6 where you're at. The paragraph that begins "We
- 7 agree."
- 8 A. Yes, I'm here.
- 9 Q. In the middle of that paragraph, the
- 10 authors write:
- 11 "However, because of the rarity of 12 ovarian cancer and the risk of recall bias in
- 13 retrospective studies, we think that despite the
- 14 limitations, the prospective cohorts included in
- 15 the analysis offered -- included in -- included in
- 16 the analysis offered important new data for
- 17 addressing this question."
- Do you agree with that statement?
- 19 A. Well, yes, because I had
- 20 specifically stated that -- that I -- we felt that
- 21 the association was -- was, in fact, there. And
- 22 they specifically said that they completely agree
- 23 with me and colleagues that our results,
- 24 particularly the analyses limited to women with

1 more than one place where she agrees.

- Q. It says what it says, right?
- 3 A. Yeah, yeah. It says what it says.
- 4 Q. All right. Thank you.
- 5 A. Yeah.
- 6 Q. You can put that aside.
- 7 A. Okay.
- 8 Q. You mentioned a moment ago a
- 9 reference to this 10 percent number that you
- 10 reported in your 1992 study, correct?
- 11 A. Yes.
- 12 Q. Is it your opinion that 10 percent
- 13 of ovarian cancers diagnosed in 2024 are caused by
- 14 talcum powder?
- 15 A. At the time I wrote that, it was
- 16 based on the risk estimates that we saw in 1992,
- 17 and at that point, that was my estimate of the
- in and at that point, that was my estimate of the
- 18 potential proportion of the incidence that could
- 19 be explained by talc exposure.
- 20 Q. My question --
- 21 A. I don't know what talc -- what's
- 22 happening now with respect to talc exposure. I
- 23 suspect that given that they have taken the
- 24 product off the market and there have been a lot

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- 1 of media around this in the news that perhaps the
- 2 prevalence of the exposure has decreased recently.
- 3 I just don't know.
- 4 Q. My question is to find out if you
- 5 have this opinion.
- 6 And is it your opinion that sitting
- 7 here today that 10 percent of ovarian cancer
- 8 diagnosed this year in 2024 will have been caused
- 9 by genital use of talcum powder?
- 10 A. Given that the most recent studies
- 11 that were done in 2016, eight years ago, found
- 12 similar risks as we found in 1992, and given that
- 13 there is a certain period of time that exposure
- 14 needs to occur in order to likely induce a
- 15 carcinogenic process, I would say that it's quite
- 16 likely that 10 percent of the incidence of ovarian
- 17 cancer today could be attributable to talc
- 18 exposure from the past.
- 19 Q. So is it your opinion that with
- 20 regard to 2000 women or 10 percent of women
- 21 diagnosed in 2024 with ovarian cancer, that they
- 22 never would have developed ovarian cancer if they
- 23 had not used talcum powder?
- 24 A. I can't -- I can't say that, but

4 reporting talc in the presence of inflammation in

1 association, other than the fact that McDonald had

- 2 tried to do that in a very small sample.3 Q. Can you cite for me any study
- A remorting tale in the presence of inflammati
- 5 the ovary before ovarian cancer has been
- 6 diagnosed?
- 7 A. I don't know of any studies like
- 8 that.
- 9 Q. Can you cite to any studies showing
- 10 an association between talc in the ovaries and
- 11 ovarian cancer risk, that is, having an increase
- 12 in risk if there's a prior finding of talc in the
- 13 ovaries?
- 14 A. I don't believe that kind of a study
- 15 has been done or really could be done in women who
- 16 don't have ovarian cancer. I don't know how you
- 17 would be able to biopsy essentially the tissue in
- 18 order to make that determination in healthy women.
- 19 Q. With regard to what you've generated 20 in this case as part of your work, we've talked
- 21 about the materials you brought with you. We
- 22 talked about your report.
- 23 Have you otherwise provided to the
- 24 attorneys representing plaintiffs in this case all

1 the materials you reviewed and all the work

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- 1 even if half of them didn't, being able to prevent
- 2 a thousand cases of ovarian cancer a year is a
- 3 huge public health intervention.
- 4 MR. HEGARTY: Let's go off the
- 5 record real quick.
- 6 (Recess: 5:19 p.m. -
- 7 5:33 p.m.)
- 8 MR. HEGARTY: We are back on
- 9 the record.
- 10 BY MR. HEGARTY:
- 11 Q. Dr. Harlow, I might jump around a
- 12 little bit on subject areas with my remaining
- 13 time.
- We talked earlier about the findings
- 15 from McDonald about talc in the ovaries of the
- 16 women studied both in the cases and the controls.
- 17 Can you cite for me any studies
- 18 showing an increase in risk of ovarian cancer in
- 19 women who have talc in their ovaries?
- 20 A. I don't believe there's any studies
- 21 that have been done that would have identified
- 22 women with ovarian cancer and talc in their
- 23 ovaries compared to women with ovarian cancer and
- 24 not talc in their ovaries and looking at the

- Page 393
- 2 product you've generated as part of your work on
- 3 this case?
- 4 A. I believe so.
- 5 Again, as of this point, yes, but I
- 6 don't know what will become available in the
- 7 future.
- 8 Q. All I'm asking you about is what you
- 9 can testify to today.
- 10 A. Yeah.
- 11 Q. Have you provided to the lawyers
- 12 representing the plaintiffs in this case all the
- 13 materials you've reviewed and generated as part of
- 14 your work on this case?
- 15 A. Yes.
- 16 Q. And do you know if Dr. Rothman ever
- 17 provided all the materials he worked on or
- 18 reviewed as part of his work on this case?
- 19 A. I don't -- I don't know what he did
- 20 in prior to him inviting me to work with him. So
- 21 I don't know what he had done and what might have
- 22 been provided. And I don't know believe there was23 anything that he did while we were working
- 24 together that would have been independent of my --

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| | Page 394 | | Page 396 |
|---------|--|----|--|
| 1 my v | | 1 | A. I haven't. |
| 1 | Q. As part of your work in this case or | 2 | Q. What information do you have as far |
| 3 othe | rwise, have you ever reviewed what your | 3 | |
| | versity, Boston University, says about ovarian | | not list talc as a risk factor for ovarian cancer? |
| | eer risk factors? | 5 | A. I would have to go and look on the |
| | A. No. | | website. |
| 7 (| Q. Have you ever reviewed what Dana | 7 | Q. Do you have any comment as to those |
| 1 | per says about ovarian cancer risk factors? | 8 | groups to the extent they don't list talc as a |
| | A. No. | 9 | |
| | Q. I'll represent to you that those | 10 | MR. TISI: Objection. Vague. |
| | sites, that the websites for those two | 11 | Ask him to speculate. |
| | lities don't list tale as a risk factor for | 12 | Go ahead. |
| | rian cancer. | 13 | THE WITNESS: I think if they |
| 14 | Do you have a response to that? | 14 | don't list it, that it would be |
| 15 | MR. TISI: Objection. Vague | 15 | appropriate for them to to list it |
| | and ambiguous and unanswerable but | 16 | as as a potential risk factor that |
| 1 | MR. HEGARTY: | 17 | perhaps may not be advisable to be used. |
| | Q. If you can answer. | 18 | That would be my recommendation. |
| 19 | MR. TISI: You can answer if | | BY MR. HEGARTY: |
| | you even understand the question. I'm | 20 | Q. You have not personally contacted |
| 1 | not sure I do. | | SGO |
| 22 | THE WITNESS: No, I understand | 22 | A. No. |
| | the question, and I am sure they may be | 23 | Q CDC or ACOG, correct? |
| | concerned, given the known litigation | 24 | A. No. |
| | | | |
| 1 1 | Page 395 that's going on, for them to come forward | 1 | Q. You make a reference in your report |
| | and put that kind of information on their | l | to a study by Taher, correct? |
| 1 | external-facing page. | 3 | A. T-a-h-e-r. Yes. |
| 4 | That would be my guess. I | 4 | Q. Please look at the end of your |
| | have no other I have no known | | report the list of citations, and to what Taher |
| | knowledge as to why they do or do not put | | study do you make reference to? |
| | that kind of information on their web | | A. Well, let me pull out the Taher |
| | on their website. | 1 | study. It's right here. |
| | MR. HEGARTY: | 9 | Q. No, I need you to look at your |
| | Q. Have you reviewed as part of your | l | report and tell me what you specifically refer to |
| 1 | in this case the list of risk factors | 1 | at the back. |
| | | 12 | A. Okay. |
| _ | rted by the Society of Gynecologic Oncology, | 13 | Q. I want to make sure we start on the |
| | GGAO, the CDC? A. SGO. | | |
| | | 15 | same page. A. I understand. |
| | Q. SGO. Thank you. The SGO, the CDC, and ACOG? | 16 | MR. TISI: Is there only one? |
| 16 | The SGO, the CDC, and ACOG? | 17 | THE WITNESS: I don't know. |
| | A. I am aware that they either do not cate it as a risk factor or have indicated | 18 | MR. HEGARTY: That's what |
| | | 18 | |
| | it is unclear whether it is a risk factor or | 20 | we're trying to find out. |
| | They may even have said it's not. I don't | l | MR. TISI: Okay. |
| 21 knov | | 21 | THE WITNESS: Taher is is |
| | Q. Have you reviewed | 22 | cited from the 2020 article. "Data on |
| | A. I haven't. | 23 | systematic review of meta-analysis of |
| 24 (| Q the list and the risk factors? | 24 | epidemiologic evidence." |

| | Page 398 | | Page 400 |
|----------------|--|----------|---|
| 1 | MR. HEGARTY: And I'll mark as | 1 | when you are there. |
| 2 | Exhibit 29 that 2020 article. | 2 | A. Uh-huh. I am there. |
| 3 | (Document marked for | 3 | Q. At the end of the first paragraph of |
| 4 | identification as Harlow Exhibit 29.) | 4 | |
| 5 | THE WITNESS: Uh-huh. | 5 | "Consistent with a previous |
| 6 | MR. HEGARTY: I'll also mark | 1 | evaluation by the IARC in 2010, the present |
| 7 | as Exhibit Number 30 the Taher 2019 | | evaluation of all currently available relevant |
| 8 | article. | | data indicates that perineal exposure to tale |
| 9 | | | powder is a possible cause of ovarian cancer in |
| 10 | · · | | humans." |
| | BY MR. HEGARTY: | 11 | Do you see where I'm reading? |
| 12 | Q. My question is: When you talked | 12 | A. Yes, I do. |
| | about Taher in your report, were you intending to | | • |
| | refer to the 2020 article or the 2019 article? | 14 | Q. Do you agree with that statement?A. Yes. |
| 15 | A. Yeah, this is I believe it's the | 15 | |
| | · | | Q. Please turn next in this paper over to page 96. Just above the "Discussion" section. |
| | same data, but I probably was reviewing the | 17 | A. Yes. |
| 17 | critical it was it was this one, yeah. The critical the "Critical review." | 18 | |
| 1 | | 1 | Q. The paragraph just before the "Discussion" section reads: |
| 19 | E | 1 | |
| | wrong. | 20 | "Overall, the graphical results |
| 21 | Q. That was my question. | | shown in this Figure 3 suggests a possible |
| 22 | A. Yeah. | | increasing trend in ovarian cancer risk with |
| 23 | Q. When you make reference to Taher | | increasing cumulative exposure to talc; however |
| 24 | over on page 13 of your report | 24 | there is also a high degree of uncertainty |
| | Page 399 | | Page 401 |
| 1 | A. Yep. | | surrounding many of the individual risk |
| 2 | Q carrying over to page 14, did you | 2 | estimates." |
| | intend to actually cite Exhibit 30, which is the | 3 | Do you agree with that statement? |
| 4 | "Critical review," but instead you cited Exhibit | 4 | MR. TISI: Objection. |
| 1 | 29, the "Data on systematic review"? | 5 | THE WITNESS: Well, as I look |
| 6 | A. (Reviews document.) | 6 | at the figure that they're referring to, |
| 7 | It looks like it's the 24 | 7 | all but two of the point estimates are |
| | case-control studies, and that would have been the | 8 | above 1 from what I can see, maybe three, |
| | article. So it was it was the critical | 9 | which is why they have a 1.28 with a very |
| | evaluation paper. | 10 | narrow confidence interval this is 24 |
| 11 | Q. So the citation in your report | 11 | studies from 1.20 to 1.37. |
| | should be to Exhibit Number 30 instead of Exhibit | 1 | BY MR. HEGARTY: |
| | Number 29? | 13 | Q. So going back to my question: Do |
| 14 | A. That's correct, and, in fact, the | | you agree with the way they characterize their |
| | odds ratio that I present in my report is the one | 1 | data as I read to you in that sentence? |
| | from 2019, the 1.28 in the abstract. Sorry. | 16 | A. Yeah. Where was that sentence |
| 17 | Q. Please note at Exhibit Number 30, | 1 | again? Sorry. |
| | the systematic review article. | 18 | Q. It's in the it's in the paragraph |
| 19 | A. The Taher article? | 1 | above "Discussion." |
| 1 | Q. The Taher article. | 20 | A. Right. Paragraph above |
| 20 | | 1 1 | "Discussion." |
| 21 | A. Yes. | 21 | |
| 21 22 | Q. And turn over to page 99. | 22 | (Reviews document.) |
| 21 22 23 | | 22 23 | |

| 1 allows us to have better precision in the risk. 2 So any one particular study is going to not have 3 the precision that we would gain by being able to 4 meta-analyze 24 of them together. 5 So when they say "there is also a 6 high degree of uncertainty surrounding many of the 7 individual risk estimates," that's the whole 8 reason why we do meta-analyzes like this, 9 especially in the context of something like this 10 association which is around 1.3 and you have 11 variability around that. 12 Q. If there is systematic error in a 13 case-control or cohort study and let me expand 14 that. 15 If there are systematic errors in 16 cases in control studies that you combine in a 17 meta-analysis, combining them in a meta-analysis 8 will not correct the systematic error in 16 cases in control studies that you combine in a 17 meta-analysis, combining them in a meta-analysis 18 will not correct the systematic error in 21 x and you have 11 unitors go on to say: 12 m A formal statistical test for trend 13 was not attempted because of the high degred 14 heterogeneity among studies noted previous 15 our meta-analysis discussed in Section 3.4. 16 Is that saying that there was 17 that they did not do a formal statistical test 18 trend, in your opinion, because of the diffe 19 across the studies that was reflected in the 20 test for heterogeneity? 2 In A. Tim not sure what they're referrin 22 to in a statistical test of trend leaves usua 23 a statistical test of trend leaves usua 23 a statistical test of trend leaves usua 23 a statistical test of trend with increasing exposure with 1 increasing risk of the disease. 5 So I'm not sure what they're talking 6 about in terms of a test of trend in the context 7 of that statement. 8 Q. Please turn over to page 98, the 9 Section 4.4 "Applying GRADE framework." 10 when you are there. 11 Q. The authors state here that they 11 A. Yes, that's what they state. 18 true on to say that: 19 on the authors gone to say that: 19 on the suddent of the correct of the difference derived from t | | Page 402 | | Page 404 |
|--|----|--|----|--|
| 2 So any one particular study is going to not have 3 the precision that we would gain by being able to 4 meta-analyze 24 of them together. 5 So when they say "there is also a 6 high degree of uncertainty surrounding many of the 7 individual risk estimates," that's the whole 8 reason why we do meta-analyses like this, 9 especially in the context of something like this 10 association which is around 1.3 and you have 11 variability around that. 12 Q. If there is systematic error in a 13 case-control or cohort study and let me expand 14 that. 15 If there are systematic errors in 16 cases in control studies that you combine in a 17 meta-analysis, combining them in a meta-analysis 18 will not correct the systematic errors, correct? 19 MR, TISE: Objection. 20 THE WITNESS: Well, I don't 21 know that I don't believe they said 22 systematic systematic error. 24 What did you say it was? Tm Page 403 1 sorry. That term you used. 2 BY MR, HEGARTY: 3 Q. And, again, let me start that 4 question over. 5 A. Yeah, because 6 Q. My question 7 A what they specifically said was 8 that "there was a high degree of uncertainty 9 surrounding many of the individual risk 10 estimates." 11 Uncertainty could relate to power. 12 It could relate to the width of the confidence 13 intervals. It could, but if doesn't it do | 1 | - | 1 | E |
| 3 the precision that we would gain by being able to 4 meta-analyze 24 of them together. 5 So when they say "there is also a 6 high degree of uncertainty surrounding many of the 7 individual risk estimates," that's the whole 8 reason why we do meta-analyses like this, 9 especially in the context of something like this 10 association which is around 1.3 and you have 11 variability around that. 12 Q. If there is systematic error in a 13 case-control or cohort study and let me expand 14 that. 15 If there are systematic errors in 16 cases in control studies that you combine in a 17 meta-analysis, combining them in a meta-analysis 8 will not correct the systematic errors, correct? 19 MR. TISI: Objection. 20 THE WTINESS: Well, I don't 21 know that I don't believe they said 22 systematic systematic error. 24 What did you say it was? Irm 1 sorry. That term you used. 2 BY MR. HEGARTY: 3 Q. And, again, let me start that 4 question over. 5 A. Yeah, because 6 Q. My question 7 A what they specifically said was 8 that "there was a high degree of uncertainty 9 surrounding many of the individual risk 10 estimates." 11 Uncertainty could relate to power. 12 It could relate to the width of the confidence 13 intervals. It could, but it doesn't it doesn't 14 suggest there's systematic error in in the 15 studies. 16 Q. My question and sorry if it was 17 confusing is not specific as to the Taher 18 study. 19 My question is that: If there are 20 is a consistent systematic error across a group of 20 the certainty of the evidence derived from the studies included in this review," correct? 17 A. Yes, that's what they state. 18 Q. They go on to say that: 19 My question is that: If there are 20 is a consistent systematic error across a group of 20 the certainty of the evidence derived from the studies including the state as a group of the care and sorty if it was 17 confusing is not specific as to the Taher 18 study. 20 The authors state here that they 21 question is that: If there are 22 is a consistent s | | | | * |
| 4 meta-analyze 24 of them together. 5 So when they say "there is also a 6 high degree of uncertainty surrounding many of the 7 individual risk estimates," that's the whole 8 reason why we do meta-analyses like this, 9 especially in the context of something like this 10 association which is around 1.3 and you have 11 variability around that. 12 Q. If there is systematic error in a 13 case-control or cohort study and let me expand 14 that. 15 If there are systematic errors in 16 cases in control studies that you combine in a 17 meta-analysis, combining them in a meta-analysis will not correct the systematic errors, correct? 19 MR. TISI: Objection. 10 MR. TISI: Objection. 11 MR. TISI: Objection. 12 My and the material of the thing of the systematic error. 13 My and the terrogeneity among studies noted previous 15 our meta-analysis discussed in Section 3.4. 16 Is that saying that there was 17 that they did not do a formal statistical test of trend is looking within a 22 system I don't believe they said 22 system I don't believe they said 23 systematic systematic error. 24 What did you say it was? I'm 18 sorry. That term you used. 29 MR. HEGARTY: 3 Q. And, again, let me start that 4 question over. 5 A. Yeah, because 6 Q. My question 7 A what they specifically said was 8 that "there was a high degree of uncertainty 9 surrounding many of the individual risk 10 estimates." 11 Uncertainty could relate to power. 12 It could relate to the width of the confidence 13 intervals. It could, but it doesn't it doesn't 14 suggest there's systematic error in in the 15 studies. 16 Q. My question and sorry if it was 17 confusing is not specific as to the Taher 18 study. 19 My question is that: If there are 20 is a consistent systematic error across a group of 20 the certainty of the evidence derived from the assessment 20 the certainty of the evidence was classified as 20 the certainty of the evidence was classified as 20 the certainty of the evidence was classified as 20 the certainty of the evi | | | | |
| 5 case-control studies that are all showing a so for a bhigh degree of uncertainty surrounding many of the reason why we do meta-analyses like this, 9 especially in the context of something like this a association which is around 1.3 and you have 11 variability around that. 12 Q. If there is systematic error in a 13 case-control or cohort study — and let me expand 14 that. 15 If there are systematic errors in 16 cases in control studies that you combine in a 17 meta-analysis, combining them in a meta-analysis will not correct the systematic errors, correct? 19 MR. TISI: Objection. 20 THE WITNESS: Well, I don't 21 know that — I don't believe they said 23 systematic — systematic error. 24 What did you say it was? I'm Page 403 1 sorry. That term you used. 25 BY MR. HEGARTY: 3 Q. And, again, let me start that 4 question over. 5 A. Yeah, because — 6 Q. My question — 7 A. — what they specifically said was 8 that "there was a high degree of uncertainty 9 surrounding many of the individual risk 10 estimates." 10 Uncertainty could relate to power. 12 It could relate to the width of the confidence 13 intervals. It could, but it doesn't — it doe | | | - | |
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| 20 is a consistent systematic error across a group of 20 the certainty of the evidence was classified as | 1 | • | 19 | "Using GRADEpro for the assessment, |
| | 20 | · - | 20 | |
| · · · · · · · · · · · · · · · · · · · | | * | 1 | • |
| 22 combining in a meta-analysis 22 Correct? | | • | | • |
| 23 A. I see. 23 MR. TISI: Objection. | 1 | | 23 | MR. TISI: Objection. |
| 24 Q that combining them in a 24 THE WITNESS: (Reviews | 24 | Q that combining them in a | 24 | |

| Page 406 document.) Can you reread that sentence where it is? I'm not seeing it. BY MR. HEGARTY: Q. Sure. | 1 2 3 | Page 408 a daily basis. Q. Please turn over to the next page, |
|---|---|---|
| Can you reread that sentence where it is? I'm not seeing it. BY MR. HEGARTY: | 2 | |
| where it is? I'm not seeing it. BY MR. HEGARTY: | | |
| BY MR. HEGARTY: | | page 99. |
| | 4 | A. Yes. |
| | 5 | Q. The paragraph at the top begins: |
| It's just after the sentence I | 6 | "Study design is a critical |
| read | 7 | component in the GRADE assessment, where |
| MR. TISI: Right there. | | randomized controlled trials (RCTs) are viewed as |
| BY MR. HEGARTY: | 9 | |
| Q under the section "Applying GRADE | | observational studies." |
| framework." The first sentence. The second | 11 | Do you agree with that statement? |
| sentence reads | 12 | A. I do. |
| A. Oh. Yes. | 13 | Q. They go on to say: |
| | _ | "As such, the evidence derived from |
| | | the observational studies in this review was |
| · · | _ | initially classified as being of low certainty |
| • | | within the GRADE framework; this was further |
| | | downgraded to very low certainty in light of the |
| | | risk of bias noted above." |
| | | Do you see where the authors |
| | | - |
| • | | A. Yeah, but again |
| - | | MR. TISI: Objection. |
| | | THE WITNESS: the next |
| | | Page 409 |
| - | 1 | sentence says: |
| <u>-</u> | | "Despite the very low |
| | | certainty assigned by the GRADE |
| | 4 | evaluation, which heavily factors |
| | 5 | evidence from RCTs." |
| | | You can't do an RCT and assign |
| · | | women to receive or not receive talc |
| • | | exposure. So the grade evaluation if it |
| • | | relies heavily on on results from |
| · · · | 10 | randomized clinical trials is going to |
| - 1 | | grade, apparently from this statement, |
| · · · · · · · · · · · · · · · · · · · | 12 | everything low that's not an RCT. |
| • | | BY MR. HEGARTY: |
| * | 14 | Q. Please look over at or back at page |
| | | 98. |
| · · | | In Footnote A at the bottom, they |
| · • | | describe the "GRADE Working Group grades"? |
| | 18 | A. Uh-huh. |
| \mathcal{E} | | Q. Correct? |
| | | A. Uh-huh. |
| | | Q. Yes? |
| | | A. Yes, I see it. Sorry. |
| - · · · · · · · · · · · · · · · · · · · | | Q. In that footnote, they describe the |
| substantially due to long-term use for decades or | | • |
| | Q "Using GRADEpro for the assessment, the certainty of the evidence was classified as very low." A. Yes, they say that. Q. Are you familiar with the GRADE framework outside of this study? A. I am not. Q. The authors a couple sentences or at least one sentence later says: "However, we deemed the findings to be subject to an appreciable risk of bias, mainly Page 407 due to the potential for recall bias in the included case control studies and the relatively short follow-up periods between exposure and outcome assessment in the included cohort studies." First of all, did I read that correctly? A. You did, but you failed to read the sentence before where they say: "First, we considered our findings from the meta-analysis to lack any serious issues with respect to inconsistency, indirectness, and imprecision." Q. Going to my question, though, did I read that statement correctly? A. Yes, you did. Q. Do you disagree with that statement? A. I disagree with the issue of recall bias. Although, again, when you're only looking at ever never with respect to talc exposure, there will possibly be some recall bias. But, again, as I've stated many times, I believe the risk of talc exposure is | Q "Using GRADEpro for the assessment, the certainty of the evidence was classified as very low." A. Yes, they say that. Q. Are you familiar with the GRADE framework outside of this study? A. I am not. Q. The authors a couple sentences or at least one sentence later says: "However, we deemed the findings to be subject to an appreciable risk of bias, mainly The page 407 due to the potential for recall bias in the included case control studies and the relatively short follow-up periods between exposure and outcome assessment in the included cohort studies." First of all, did I read that correctly? A. You did, but you failed to read the sentence before where they say: "First, we considered our findings from the meta-analysis to lack any serious issues with respect to inconsistency, indirectness, and imprecision." Q. Going to my question, though, did I read that statement correctly? A. Yes, you did. Q. Do you disagree with that statement? A. I disagree with the issue of recall bias. Although, again, when you're only looking at ever never with respect to talc exposure, there will possibly be some recall bias. But, again, as I've stated many times, I believe the risk of talc exposure is |

| | Page 410 | | Page 412 |
|--|---|--|--|
| 1 | "We have little confidence in the | 1 | A. Yes. |
| 2 | effect estimate: the true effect is likely to be | 2 | Q. Assume for purpose of my question |
| 1 | substantially different from the estimate of | 3 | that the average age of women starting talcum |
| | effect." | 4 | powder use on a regular basis is age 20, and the |
| 5 | Did I read that correctly? | 5 | average age of a tubal ligation and/or a |
| 6 | A. You did. | 6 | hysterectomy is in the 40s. |
| 7 | Q. So the authors in this study | 7 | Is that 20 years of use |
| 8 | concluded that their evidence with regard to | 8 | insufficient, in your view, to increase those |
| 9 | talcum powder use and ovarian cancer is of very | 9 | women's risk of ovarian cancer? |
| 10 | low certainty, correct? | 10 | A. Not necessarily. 20 years of use |
| 11 | MR. TISI: Objection. | 11 | every day in a patent genital tract until that |
| 12 | THE WITNESS: That was their | 12 | time is a substantial amount of exposure, in my |
| 13 | opinion. | 13 | view. |
| 14 | BY MR. HEGARTY: | 14 | Q. In my hypothetical, if that is the |
| 15 | Q. Did you read when you sorry. | 15 | nature of use in the studies that we looked at |
| 16 | Strike that. | 16 | that have looked at patent and unpatent tubes, how |
| 17 | Did you see when you read the Health | 17 | is then an emphasis on the finding findings of |
| | Canada screening assessment that they rely or that | 18 | unpatent tubes a noteworthy finding? |
| 19 | they reference this Taher study? | 19 | MR. TISI: Objection. |
| 20 | A. I believe they reference a lot of | 20 | BY MR. HEGARTY: |
| 21 | studies. I don't know. I mean, I have the Health | 21 | Q. If you can understand my question? |
| | Canada report and I I don't dispute that they | 22 | MR. TISI: Misstates his |
| 23 | that they reference this study. | 23 | testimony. |
| 24 | Q. Do you see where it says under the | 24 | Go ahead. |
| | Page 411 | | Page 413 |
| 1 | "Sources of funding" part of this paper that: | 1 | THE WITNESS: Why don't you |
| 2 | "This work was supported by Health | 2 | repeat that question, please. |
| 1 2 | | | |
| 1 | Canada as part of their Chemicals Management Plan | 3 | BY MR. HEGARTY: |
| 4 | via contract number" and they list the contract | 3 4 | BY MR. HEGARTY: Q. Sure. |
| 4 5 | via contract number" and they list the contract number? | 3 4 5 | BY MR. HEGARTY: Q. Sure. If my hypothetical is accurate and |
| 4 5 6 | via contract number" and they list the contract number? A. Yes. | 3 4 5 6 | BY MR. HEGARTY: Q. Sure. If my hypothetical is accurate and the women studied in those studies that have |
| 4 5 6 7 | via contract number" and they list the contract number? A. Yes. Q. "To Risk Scientists International | 3 4 5 6 7 | BY MR. HEGARTY: Q. Sure. If my hypothetical is accurate and the women studied in those studies that have looked at patent and unpatent tubes had 20 years |
| 4 5 6 7 8 | via contract number" and they list the contract number? A. Yes. Q. "To Risk Scientists International (RSI), Ottawa Canada Ontario, Canada"? | 3 4 5 6 7 8 | BY MR. HEGARTY: Q. Sure. If my hypothetical is accurate and the women studied in those studies that have looked at patent and unpatent tubes had 20 years of talc exposure prior to having tubal ligation or |
| 4 5 6 7 8 9 | via contract number" and they list the contract number? A. Yes. Q. "To Risk Scientists International (RSI), Ottawa Canada Ontario, Canada"? A. Yes, I see that. | 3 4 5 6 7 8 9 | BY MR. HEGARTY: Q. Sure. If my hypothetical is accurate and the women studied in those studies that have looked at patent and unpatent tubes had 20 years of talc exposure prior to having tubal ligation or hysterectomy, how is it noteworthy to compare |
| 4 5 6 7 8 9 | via contract number" and they list the contract number? A. Yes. Q. "To Risk Scientists International (RSI), Ottawa Canada Ontario, Canada"? A. Yes, I see that. Q. Does that indicate to you that | 3 4 5 6 7 8 9 | BY MR. HEGARTY: Q. Sure. If my hypothetical is accurate and the women studied in those studies that have looked at patent and unpatent tubes had 20 years of talc exposure prior to having tubal ligation or hysterectomy, how is it noteworthy to compare those women to women with patent tubes? |
| 4 5 6 7 8 9 10 11 | via contract number" and they list the contract number? A. Yes. Q. "To Risk Scientists International (RSI), Ottawa Canada Ontario, Canada"? A. Yes, I see that. Q. Does that indicate to you that Health Canada provided funding to do this study? | 3 4 5 6 7 8 9 10 11 | BY MR. HEGARTY: Q. Sure. If my hypothetical is accurate and the women studied in those studies that have looked at patent and unpatent tubes had 20 years of talc exposure prior to having tubal ligation or hysterectomy, how is it noteworthy to compare those women to women with patent tubes? MR. TISI: Objection. |
| 4 5 6 7 8 9 10 11 12 | via contract number" and they list the contract number? A. Yes. Q. "To Risk Scientists International (RSI), Ottawa Canada Ontario, Canada"? A. Yes, I see that. Q. Does that indicate to you that Health Canada provided funding to do this study? A. Yes, they they did. | 3 4 5 6 7 8 9 10 11 12 | BY MR. HEGARTY: Q. Sure. If my hypothetical is accurate and the women studied in those studies that have looked at patent and unpatent tubes had 20 years of talc exposure prior to having tubal ligation or hysterectomy, how is it noteworthy to compare those women to women with patent tubes? MR. TISI: Objection. BY MR. HEGARTY: |
| 4 5 6 7 8 9 10 11 12 13 | via contract number" and they list the contract number? A. Yes. Q. "To Risk Scientists International (RSI), Ottawa Canada Ontario, Canada"? A. Yes, I see that. Q. Does that indicate to you that Health Canada provided funding to do this study? A. Yes, they they did. I don't believe that I believe | 3 4 5 6 7 8 9 10 11 12 13 | BY MR. HEGARTY: Q. Sure. If my hypothetical is accurate and the women studied in those studies that have looked at patent and unpatent tubes had 20 years of talc exposure prior to having tubal ligation or hysterectomy, how is it noteworthy to compare those women to women with patent tubes? MR. TISI: Objection. BY MR. HEGARTY: Q. If you can understand do you |
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| 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 | via contract number" and they list the contract number? A. Yes. Q. "To Risk Scientists International (RSI), Ottawa Canada Ontario, Canada"? A. Yes, I see that. Q. Does that indicate to you that Health Canada provided funding to do this study? A. Yes, they they did. I don't believe that I believe Health Canada is a governmental agency. Okay. It's not a private foundation. It's a governmental agency. Just like we are funded here in the United States by the National Institutes of Health for a lot of research that we do. | 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 | BY MR. HEGARTY: Q. Sure. If my hypothetical is accurate and the women studied in those studies that have looked at patent and unpatent tubes had 20 years of talc exposure prior to having tubal ligation or hysterectomy, how is it noteworthy to compare those women to women with patent tubes? MR. TISI: Objection. BY MR. HEGARTY: Q. If you can understand do you understand my question? A. Yeah. I think you're you're assuming that the studies looked only at women who were exposed during times when they had patent tubes, and then looking at women who are only |
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| 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 | via contract number" and they list the contract number? A. Yes. Q. "To Risk Scientists International (RSI), Ottawa Canada Ontario, Canada"? A. Yes, I see that. Q. Does that indicate to you that Health Canada provided funding to do this study? A. Yes, they they did. I don't believe that I believe Health Canada is a governmental agency. Okay. It's not a private foundation. It's a governmental agency. Just like we are funded here in the United States by the National Institutes of Health for a lot of research that we do. Q. We've been talking today about the studies reporting on relative risk or odds ratios between women with patent and women with unpatent | 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 t21 22 23 | BY MR. HEGARTY: Q. Sure. If my hypothetical is accurate and the women studied in those studies that have looked at patent and unpatent tubes had 20 years of talc exposure prior to having tubal ligation or hysterectomy, how is it noteworthy to compare those women to women with patent tubes? MR. TISI: Objection. BY MR. HEGARTY: Q. If you can understand do you understand my question? A. Yeah. I think you're you're assuming that the studies looked only at women who were exposed during times when they had patent tubes, and then looking at women who are only exposed during times when their genital tract was closed. Is that what you're saying? |

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| Page | 414 |

- 1 differences between the group who used talc for 20
- 2 years prior to having tubal ligation or
- 3 hysterectomy and those that had patent tubes, what
- 4 do you explain the differences to be?
- Well, I believe others have
- 6 explained the possibility that if they're using it
- 7 and they do not have patent tubes, it does not
- 8 preclude them from exposure, particularly from
- 9 inhalation.
- 10 Q. Is it your opinion that inhalation
- 11 of talcum powder use can cause ovarian cancer?
- 12 There's some evidence that it was --
- 13 that it's a possibility. I believe it was -- was
- 14 it Schildkraut's article that discussed that?
- 15 One of the articles did discuss that
- 16 as a possibility, and I didn't do an extensive
- 17 search on -- on inhalation of talc and its impact
- 18 specifically on ovarian cancer.
- Do you have an opinion one way or
- 20 another as to whether inhalation of talc can cause
- 21 ovarian cancer?
- 22 I don't have an opinion at this
- 23 point, but you've tweaked my interest.
- 24 You had -- you don't make any

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Page 417

- Well, because most of the studies
- 2 that have looked at this have shown that it is not
- 3 as strong a risk factor as that among women who
- 4 apply it daily on a regular basis.
- 5 You said you reported on that data O. 6 in at least one of your prior studies, correct?
 - A. We have, yes.
- 8 Is that appropriate data to look at
- 9 when evaluating whether there's a risk of ovarian
- 10 cancer with talcum powder use?
- A. I believe so. 11
- 12 O. We talked a moment -- talked earlier
- 13 in the day about whether it is necessary for talc
- 14 to reach the ovary for purposes of your biologic
- 15 plausibility assessment, and you also referenced
- 16 that talc can get to the fallopian tubes.
- 17 Do you recall that discussion?
- 18 A. Yes.
- 19 O. Is it necessary for purposes of your
- 20 biologic plausibility opinion that talc at least
- 21 reached the fallopian tube?
- 22 I think it would be reasonable to.
- 23 If there were no evidence of talc reaching the
- 24 fallopian tubes, I would -- I would reassess that,
- Page 415

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- 1 reference in your report to studies that have
- 2 looked at talc-dusted diaphragms or talc-dusted
- 3 condoms in ovarian cancer risk, correct?
- In my -- in my previous research, I
- 5 definitely discuss that. In the report, we -- we
- 6 focus on -- on direct perineal application.
- 7 Although I would not be surprised if within my
- 8 report on some of these particular studies we
- 9 talked about the issue of exposure on diaphragms
- 10 or condoms.
- 11 But I believe in most of the
- 12 research that I've looked at, the risk is lower in
- 13 those women. Probably because of the infrequent
- 14 nature of the exposure.
- 15 My question is not what the risk is
- 16 that's or has been reported in the study.
- 17 My question is: Did you do an
- 18 analysis in your report in this case of the
- 19 studies that looked at the risk of ovarian cancer
- 20 from women using talc-dusted diaphragms or
- 21 talc-dusted condoms?
- 22 I did not specifically put a section
- 23 in my report about that particular risk.
- 24 Why did you not do that?

- 1 but the fact is there is.
 - MR. TISI: May I ask how much
- 3 time we have?
- 4 MR. HEGARTY: Let's go off the
- 5 record.
 - (Recess: 6:01 p.m. -
 - 6:02 p.m.)
 - MR. HEGARTY: We're back on
- 9 the record.
- 10 I have some amount of time
- 11 left, 16 minutes, I believe, that we
- 12 talked about. I'm going to reserve that
- 13 time for any further questioning once
- plaintiffs' counsel is finished asking or 14
- 15 doing his direct examination of
- Dr. Harlow. 16
- 17 MR. TISI: And we will, you
 - know, I will be flexible with you as long as it's not unreasonable.
 - MR. HEGARTY: Thank you.
- (Recess: 6:03 p.m. -21
 - 6:04 p.m.)
- 23 // 24 //

18 19

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| Page 41 | 8 Page 420 |
|---|---|
| 1 EXAMINATION | 1 A. I've looked at |
| 2 BY MR. TISI: | 2 MR. HEGARTY: Do you have |
| 3 Q. Doctor, I'm Chris Tisi. I am the | 3 copies of any studies you're going to |
| 4 attorney who is the who has retained you to | 4 use? |
| 5 give your expert opinion in this case. | 5 MR. TISI: Yeah. |
| 6 So let me just start with the big | 6 MR. HEGARTY: Do you have |
| 7 picture and perhaps maybe we can maneuver to son | ne 7 copies for me? |
| 8 specific areas. | 8 MR. TISI: I do. |
| 9 You were asked a lot of questions | 9 MR. HEGARTY: I was going to |
| 10 about I think you talked about Weiss's study | 10 say I can find copies if I need to, but I |
| 11 and different studies over the course of the past | 11 will wait. |
| 12 40, 50 years. I'm going to bring you to today and | 12 BY MR. TISI: |
| 13 just ask you a big picture question. | 13 Q. I'm going to use by way of |
| Based upon what's known today and | 14 example I'm going to show you a study or I'm |
| 15 having considered all the things you considered | 15 sorry. Maybe this is one in which I don't. |
| 16 over the past 50 years of research, do you | MR. HEGARTY: Which one is it? |
| 17 continue to believe to a reasonable degree of | MR. TISI: This is the 2021. |
| 18 scientific certainty that talc is a cause of | 18 This one. |
| 19 epithelial ovarian cancer? | MS. PARFITT: Which one? |
| 20 MR. HEGARTY: Objection to | 20 O'Brien? |
| 21 form. | 21 MR. TISI: 2021. |
| THE WITNESS: I do. | MR. HEGARTY: Who are the |
| 23 BY MR. TISI: | 23 authors? |
| Q. Okay. Did anything that counsel | 24 MR. TISI: It's O'Brien |
| Page 41 1 told asked you about today change that opinion 2 at all? 3 MR. HEGARTY: Objection to 4 form. | Page 421 Weinberg, D'Aloisio Moore, and Sandler. MR. HEGARTY: I think I have a copy. If you don't have a copy, I think I have one. I can find it. |
| 5 THE WITNESS: No. | 5 MR. TISI: Okay. I'm going to |
| 6 BY MR. TISI: | 6 have this marked as Plaintiff's Exhibit |
| 7 Q. Okay. Do you believe it's | 7 Number 1. |
| 8 biologically plausible that talc can reach the | 8 Do you have a copy of that? |
| 9 ovaries, can cause inflammation resulting in | 9 THE WITNESS: Yes, I do. |
| 10 cellular changes, enter the ovary, and and it's | 10 MR. TISI: Can I mark yours as |
| 11 biologically plausible that that is in the chain | 11 Exhibit Number 1, please? |
| 12 of events leading to ovarian cancer? | 12 (Document marked for |
| 13 MR. HEGARTY: Objection to | 13 identification as Exhibit P1.) |
| 14 form of the question. | 14 MR. HEGARTY: Do you have a |
| 15 THE WITNESS: It's | 15 copy? |
| 16 biologically plausible. | 16 MR. TISI: You can read over |
| 17 BY MR. TISI: | his shoulder if you don't mind. |
| 18 Q. Okay. And so you were asked a lot | 18 MR. HEGARTY: Yeah, I do want |
| 19 of questions today about Dr. O'Brien. | to when you're done. Is your copy marked |
| 20 Did you look at Dr. O'Brien's | 20 on? |
| 21 research? Did you look at Dr. O'Brien's research | 21 MR. TISI: I would give you my |
| 22 over over time? | 22 copy. |
| 23 A. Yes. | 23 MR. HEGARTY: I just want to |
| 24 Q. Okay. | 24 look at back over it. |
| 21 Q. Okuy. | 2. TOOK at ouch over it. |

| | Page 422 | | Page 424 |
|----------|--|----|--|
| 1 | MR. TISI: Sure. | 1 | 1994. |
| 2 | MR. HEGARTY: Beyond what | 2 | BY MR. TISI: |
| 3 | you're asking him about. | 3 | Q. It says: |
| 4 | MR. TISI: No problem. | 4 | "Additional or more severe adverse |
| 5 BY | MR. TISI: | 5 | effects could occur if the talc contains asbestos, |
| 6 | Q. I'm going to this is an article | 6 | a known carcinogen sometimes mined in the same |
| 7 that | t Dr. O'Brien and colleagues wrote on "The | 7 | location as talc." |
| 8 asso | ociation between douching, general talc use, | 8 | Do you see that? |
| 9 and | the risk of prevalent and incident cervical | 9 | A. Yes, I do. |
| 10 can | cer." | 10 | MR. HEGARTY: Objection to the |
| 11 | Have you seen this article before? | 11 | form. |
| 12 | A. Yes. | 12 | BY MR. TISI: |
| 13 | Q. Okay. I'm going to refer you to the | 13 | Q. Okay. Does that add to the biologic |
| 14 seco | ond page. She says she describes she | 14 | plausibility that talc is a cause of ovarian |
| 15 des | cribes her own research as well as biologic | 15 | cancer and is that something that you wrote about |
| 16 plai | usibility, and I'm going to read it to you and | 16 | in your article in 1989? |
| 17 ask | whether you agree with it. Okay? | 17 | A. Yes. |
| 18 | A. Yes. | 18 | MR. HEGARTY: Objection to the |
| 19 | Q. It says: | 19 | form. |
| 20 | "Genital talc use could also | 20 | THE WITNESS: It is something |
| 21 plai | usibly contribute to cervical cancer risk." | 21 | that I mentioned in 1989 in my article. |
| 22 | She's talking about cervical cancer | 22 | BY MR. TISI: |
| 23 the | re, right? | 23 | Q. And then she goes on to say: |
| 24 | A. Uh-huh. | 24 | "The epidemiologic literature |
| | Page 423 | | Page 425 |
| 1 | Q. Okay. But then she goes on to say: | 1 | supports a possible positive association between |
| 2 | "Talc applied to underwear, sanitary | | general talc use and ovarian cancer." |
| 3 nap | okins, diaphragms, or directly to the perineal | 3 | Do you see that? |
| | ion can enter the vagina and travel up the | 4 | A. Yes, Do I. |
| 5 rep | roductive tract." | 5 | Q. And if you look at the citation, she |
| 6 | Is that consistent with what you | 6 | cites her own pooled analysis that counsel was |
| 7 des | cribed in your literature 20, 30 years ago? | | asking you about before, correct? |
| 8 | MR. HEGARTY: Objection to the | 8 | A. That's correct, and the Terry study. |
| 9 | form. | 9 | Q. Okay. Now, you |
| 10 | THE WITNESS: Yes. | 10 | A. Are we done with this? |
| 11 BY | MR. TISI: | 11 | Q. Yes, we are. |
| 12 | Q. Okay. Secondly says: | 12 | A. Okay. |
| 13 | "Talc particles may act as | 13 | Q. In fact, she's made that that |
| 14 irrit | tants, inciting an inflammatory response and | | comment on more than one occasion since publishing |
| 1 | entially affecting individuals' | | her article, correct? |
| _ | ceptibility." | 16 | MR. HEGARTY: Objection to the |
| 17 | Do you see that? | 17 | form. |
| 18 | A. I do. | 18 | THE WITNESS: I would need to |
| 19 | Q. Okay. Is that something you wrote | 19 | see it. |
| | out 20, 30, or 40 years ago? | 20 | MR. TISI: Okay. Okay. I |
| 21 | MR. HEGARTY: Objection to the | 21 | have another. I have another copy of it. |
| 22 | form. | 22 | Here you go. |
| 23 | THE WITNESS: I for sure | 23 | MR. HEGARTY: Okay. I'll give |
| 24 | mentioned it in my review article in | 24 | you your copy back. Is that Exhibit |
| | , | | J J |

| | D 446 | | D 400 |
|----------------|---|----------|---|
| 1 | Page 426 Number 1? | 1 | Page 428 questions by counsel about whether you had eve |
| 2 | | l . | made any effort to educate your colleagues with |
| 3 | THE WITNESS: Oh, I've got the one that says exhibit on it. Here | l . | the medical and scientific community about the |
| | • | 4 | · |
| 4 5 | you go. Oh, it's Exhibit 1. Do I give | 5 | Do you remember those questions? |
| 5 | you this back? | | MR. HEGARTY: Objection to |
| | BY MR. TISI: | 6 7 | form. |
| 7 | Q. No, just leave it. | 8 | |
| 8 | All right. So | l | THE WITNESS: Yes, I remember |
| 9 | MR. HEGARTY: Are you using | 10 | those questions. BY MR. TISI: |
| 10 | that as P1 or 1? | 11 | |
| 11 | MR. TISI: P1. Plaintiff's 1. | l | Q. Okay. Now, taking those two things, |
| 12 | MR. HEGARTY: I just want to | l . | together talking about the biologic plausibility |
| 13 | make sure that when we read the record we | | of talc and ovarian cancer and the question of |
| 14 | don't | l . | letting people know about your views, is that |
| 15 | MR. TISI: Yeah, if I have to | l . | something you did in the published medical |
| 16 | go back and follow your system, I won't | l . | literature before you were ever contacted by me |
| 17 | be able to. | | Ms. Parfitt, or anybody else? |
| | BY MR. TISI: | 18 | MR. HEGARTY: Objection to the |
| 19 | Q. Okay. So let me go back and ask you | 19 | form. |
| 1 | some things. | 20 | THE WITNESS: Well, in my |
| 21 | He asked you some questions about | 21 | published article, my 1989 article, my |
| 1 | whether you were a toxicologist, whether you were | 22 | 1992 article, my 1994 article and the |
| | a cellular biologist, whether you're a medical | 23 | article I did with Dr. Cramer in 1999, we |
| 24 | doctor. | 24 | always ended with our belief that this |
| | Page 427 | | Page 429 |
| 1 | Remember all those questions? | 1 | was an exposure that women should avoid. |
| 2 | A. Yes. | 2 | |
| 3 | Q. Okay. Doctor, in the course of | 3 | Q. And you talked about asbestos |
| l | being an epidemiologist for your entire career, de | l . | |
| 5 | | 5 | A. Yes. |
| 0 | evidence to evaluate in connection with the | 6 | Q. You talked about biologic |
| / | statistical evidence that you gather as an | | plausibility including the migration, correct? |
| | epidemiologist? | 8 | MR. HEGARTY: Objection to the |
| 9 | MR. HEGARTY: Objection to the | 9 | form. |
| 10 | | 10 | THE WITNESS: As I do in all |
| 11 | THE WITNESS: It's the | 11 | of my research articles. |
| 12 | * | | BY MR. TISI: |
| 13 | | 13 | Q. You talked about you talked about |
| 14 | & · | | all the things that counsel asked you about today |
| 15 | | | long before you were ever retained by us, true? |
| 16 | S | 16 | MR. HEGARTY: Objection to the |
| 17 | • | 17 | form. |
| 18 | • | 18 | THE WITNESS: That's correct. |
| 19 | | | BY MR. TISI: |
| | studies or cell-based studies, or other | 20 | Q. Okay. For example, let me show you |
| 20 | · | l . | |
| 20 21 | studies that would provide evidence that | | what I have marked as Exhibit Number P2, which is |
| 20 21 22 | studies that would provide evidence that the association makes biological sense. | 22 | your article from 1989. |
| 20 21 22 | studies that would provide evidence that the association makes biological sense. BY MR. TISI: | 22 23 | |

| | D (20) | | D 422 |
|----|--|----|---|
| 1 | Page 430 BY MR. TISI: | 1 | Q. Okay. So one of the things you |
| 2 | Q. And I'm not going to go over every | | talked about in your early literature is whether |
| | aspect of it, but you're familiar with this | | or not asbestos was in these products that were |
| | article, correct? | | used perineally, correct? |
| 5 | A. Yes. | 5 | MR. HEGARTY: Objection to the |
| 6 | Q. Okay. And this is a study called "A | 6 | form. |
| | Case-Control Study of Borderline Ovarian Tumors: | 7 | THE WITNESS: That is |
| | The Influence of Perineal Exposure to Talc," | 8 | correct, and I believe in the body of the |
| 1 | correct? | 9 | discussion I talk about the evidence for |
| 10 | A. Yes. | 10 | that. |
| 11 | | | BY MR. TISI: |
| 12 | Q. Okay. And this was 1989, correct? A. That's correct. | 12 | |
| | | | Q. Okay. Let's go to the next one, |
| 13 | Q. Okay. George Bush the first was | | 1982, which I think was previously marked, but I'm |
| l | president, right? | | going to mark it again because I don't want to dig |
| 15 | A. I don't recall. (Laugh). | | through my stuff. A. 1992? |
| 16 | Q. Long time ago, fair? A. Yes. | 16 | |
| 17 | | 17 | Q. 1992. This is an article "Perineal |
| 18 | Q. Okay. And you write at the end of | | Exposure to Talc and Ovarian Cancer Risk," Bernard |
| l | your and you talk about that there was an | | Harlow, and this will be Exhibit P3. |
| | increased incidence in borderline ovarian tumors | 20 | (Document marked for |
| | in women who had been exposed to deodorizing | 21 | identification as Exhibit P3.) |
| | powders, correct? | | BY MR. TISI: |
| 23 | A. It was not incidence. It was risk. | 23 | Q. And what was the significance of |
| 24 | Q. Risk. True? | 24 | this study, Doctor? |
| | Page 431 | | Page 433 |
| 1 | A. Yes. | 1 | A. Well, I believe this was one of the |
| 2 | Q. Okay. But I want to refer you to | | one of the first studies to really try to tease |
| | the very end of the article and, again, you were | | out the dose-response association with talc |
| | not retained as an expert at the time, correct? | | applications by looking at it excluding use after |
| 5 | A. Correct. | | hysterectomy or tubal ligation and during |
| 6 | Q. In fact, there was I'm going to | | non-ovulatory months where we see an importan |
| | represent to you that no case of ovarian cancer | | dose response. |
| | and talc wasn't ever filed until 2009. | 8 | Q. And you saw anywhere between a |
| 9 | All your published literature, with | | you saw an increased risk in dealing with women |
| l | the exception of the letter to the editor, was | | with patent intact reproductive tracts of ovarian |
| | published before there was any talc litigation, | | cancer, true? |
| | correct? | 12 | MR. HEGARTY: Objection to the |
| 13 | A. Yes. | 13 | form. |
| 14 | Q. Okay. And you write at the end, the | 14 | THE WITNESS: Yes, but it |
| | last sentence. I'll read it into the record. | 15 | wasn't it wasn't specifically asking |
| 16 | "Although these data need | 16 | about that. It was actually calculating |
| 1 | replication, they raise the possibility that the | 17 | applications that were used during |
| | risk of ovarian tumors in women who apply | 18 | periods when there was a patent genital |
| 19 | deodorizing powder to the perineum may not relate | 19 | tract. |
| 1 | to talc per se but rather to asbestos | | BY MR. TISI: |
| 21 | contamination and/or a substances or substances | 21 | Q. Okay. And that brings me to a |
| 1 | used specifically for deadorization " | 22 | question that counsel was asking a lot of |
| 1 | used specifically for deodorization." | | - |
| | Do you see that? | | question that counsel was asking a lot of questions about. He asked you about years of use. He |

| | D 424 | | D 424 |
|---|---|--|--|
| 1 | Page 434 asked you about frequency of use. | 1 | Page 436 form. |
| 2 | | 2 | THE WITNESS: I did not think |
| 3 | | 3 | of it as the talc industry. I thought of |
| 4 | | 4 | it as the Food and Drug Administration |
| 5 | | 5 | and the International Society of |
| 6 | | 6 | Regulatory Toxicology & Pharmacology. I |
| 7 | • | 7 | did not |
| 8 | | 8 | BY MR. TISI: |
| 9 | • | 9 | Q. At the time. |
| 10 | | 10 | A. At the time, I did not think to |
| 11 | | - | myself, oh, this is an industry-sponsored |
| 12 | • | | conference. |
| | get an accurate assessment of exposure. BY MR. TISI: | | |
| | | 13 | Q. Okay. |
| 14 | | 14 | A. I basically wanted I was pleased |
| | do in this particular study, correct? | | to be invited, was pleased to have the opportunity |
| 16 | | l | to convey my findings, with the hope that it would |
| 17 | | l | lead to potential mitigation of the exposure. |
| | study, you state again, this is long before | 18 | Q. Okay. And so when you went into |
| 19 | \mathcal{E} | | this when you went into this meeting, you were |
| 20 | 1 1 5 | l | pretty clear that not only was there an |
| | for ovarian cancer, any potentially harmful | | association in people who had been exposed |
| | exposures should be avoided, particularly those | l | women who had been exposed, but that for |
| | with limited benefits. For this reason, we | | precautionary reasons they shouldn't be using it, |
| 24 | discourage the use of talc in genital hygiene, | 24 | true? |
| | Page 435 | 1 | Page 437 |
| | particularly as a daily habit." | 1 | MR. HEGARTY: Objection to the |
| 2 | | 2 | form. |
| 3 | | 3 | THE WITNESS: I had stated |
| 4 | C | 4 | |
| 5 | VOIL did VOILEVER fell the medical and scientific | _ | that in my 1989 article. I had stated |
| | | 5 | that in my 1992 article. And when I went |
| | community about your point of view, you actually | 6 | that in my 1992 article. And when I went into the conference in 1994, my views had |
| 7 | community about your point of view, you actually published in the peer-reviewed literature about | 6 7 | that in my 1992 article. And when I went into the conference in 1994, my views had not changed. |
| 7 8 | community about your point of view, you actually published in the peer-reviewed literature about that, correct? | 6 7 8 | that in my 1992 article. And when I went into the conference in 1994, my views had not changed. BY MR. TISI: |
| 7 8 9 | community about your point of view, you actually published in the peer-reviewed literature about that, correct? MR. HEGARTY: Objection to the | 6 7 8 9 | that in my 1992 article. And when I went into the conference in 1994, my views had not changed. BY MR. TISI: Q. Now, in the article itself and do |
| 7 8 9 10 | published in the peer-reviewed literature about that, correct? MR. HEGARTY: Objection to the form. Misstates my question. | 6 7 8 9 10 | that in my 1992 article. And when I went into the conference in 1994, my views had not changed. BY MR. TISI: Q. Now, in the article itself and do you have a copy of the article in front of you? |
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| | Page 438 | | Page 440 |
|--|--|--|---|
| 1 | MR. HEGARTY: I trust you. | 1 | MR. HEGARTY: Objection to |
| 2 | THE WITNESS: Yes, that's | 2 | form. |
| 3 | this. Yes, that's the summary. The | 3 | BY MR. TISI: |
| 4 | summary by Rapporteur Jelleff Carr. | 4 | Q. Okay. Did you ultimately write a |
| 5 | BY MR. TISI: | 5 | full review of what it was that you that you |
| 6 | Q. Now, in here it says on page 215 | | presented at the meeting in 2014? |
| 7 | on the left-hand side, it says: | 7 | A. Yes. |
| 8 | "Dr. Hartge (National Cancer | 8 | Q. Okay. In fact, just to be just |
| | Institute) and Dr. Harlow (Harvard University) | 9 | to be clear, the only reference in this article |
| 1 | presented a review of epidemiologic studies | | was was to whom? |
| | including their own original studies pertaining | 11 | A. Dr. Rothman. |
| 1 | to perineal talc exposure and ovarian cancer | 12 | Q. Okay. Somebody who counsel implied |
| | risk." | | may have been statistically unsophisticated. |
| 14 | A. Can you show me where that is, | 14 | Would you ever classify Dr. Rothman |
| | please? | | or yourself as statistically unsophisticated? |
| 16 | Q. On the left-hand side. | 16 | MR. HEGARTY: Objection to the |
| 17 | A. Yeah. | 17 | form. |
| 18 | Q. The last full paragraph on page 215. | 18 | THE WITNESS: No. |
| 19 | A. Oh, 215. I'm sorry. | | BY MR. TISI: |
| 20 | Okay. Dr. Hartge and Dr. Harlow. I | 20 | Q. Okay. Between the two of you, would |
| | got the paragraph. Go ahead. | | you maybe have published perhaps anywhere between |
| 22 | Q. Did this article at all explain what | | 500 and a thousand articles in the peer-reviewed |
| | your presentation was so that people subsequent to | | literature? |
| 1 | this hearing could hear about your presentation | 24 | MR. HEGARTY: Objection to |
| | | | |
| | Page 439 | | Page 441 |
| 1 | Page 439 about the risks? | 1 | Page 441 form. |
| - | about the risks? | 1 2 | form. |
| 2 | about the risks? MR. HEGARTY: Objection to the | 2 | _ |
| - | about the risks? | 2 | form. THE WITNESS: Yes. BY MR. TISI: |
| 2 3 | about the risks? MR. HEGARTY: Objection to the form. | 2 3 4 | form. THE WITNESS: Yes. BY MR. TISI: Q. Okay. He's published textbooks and |
| 2 3 4 | about the risks? MR. HEGARTY: Objection to the form. THE WITNESS: No. BY MR. TISI: | 2 3 4 5 | form. THE WITNESS: Yes. BY MR. TISI: Q. Okay. He's published textbooks and the textbooks that are used in medical schools |
| 2 3 4 5 | about the risks? MR. HEGARTY: Objection to the form. THE WITNESS: No. BY MR. TISI: Q. Okay. | 2 3 4 5 6 | form. THE WITNESS: Yes. BY MR. TISI: Q. Okay. He's published textbooks and the textbooks that are used in medical schools throughout the country? |
| 2 3 4 5 6 7 | about the risks? MR. HEGARTY: Objection to the form. THE WITNESS: No. BY MR. TISI: Q. Okay. A. There was nothing other than | 2 3 4 5 | form. THE WITNESS: Yes. BY MR. TISI: Q. Okay. He's published textbooks and the textbooks that are used in medical schools throughout the country? A. And in schools of public health |
| 2 3 4 5 6 7 | about the risks? MR. HEGARTY: Objection to the form. THE WITNESS: No. BY MR. TISI: Q. Okay. A. There was nothing other than indicating that we presented original research | 2 3 4 5 6 7 | form. THE WITNESS: Yes. BY MR. TISI: Q. Okay. He's published textbooks and the textbooks that are used in medical schools throughout the country? A. And in schools of public health MR. HEGARTY: Objection to |
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| | Page 442 | | Page 444 |
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| 1 | yield any additional concern. | 1 | Q. And you'll see at the very first |
| 2 | Do you see that at the very end of | 2 | part of it, it says it says: |
| l . | the paragraph? | 3 | "Presented, in part" |
| 4 | A. Yes. | 4 | Footnote 1 says: |
| 5 | "For epidemiology, further | 5 | "Presented, in part, at the |
| 1 | refinements may be possible in the selection and | 6 | International Society of Regulatory Toxicology and |
| 1 | characterization of control subjects and in the | 7 | Pharmacology," referring to this meeting, correct? |
| 1 | accounting of possible confounders and biases. | 8 | A. Yes. |
| | However, epidemiologic studies have provided weak | 9 | Q. Okay. And it was your goal here is |
| 1 | and conflicting risk signals for this association, | | to to communicate what it was you were trying |
| 1 | and it is unlikely that further studies may prove | | to communicate at that meeting, correct? |
| 1 | adequate to raise concern at a level sufficient to | 12 | MR. HEGARTY: Objection to the |
| 13 | warrant regulatory or public health measures." | 13 | form. |
| 14 | Q. In fact in fact, after this | 14 | THE WITNESS: Yes. |
| 1 | particular study, there were literally dozens of | _ | BY MR. TISI: |
| | studies that were funded by by institutions | 16 | Q. Okay. And if you look, it talks |
| 1 | throughout the country, including National Cancer | | about, for example, on the right-hand side studies |
| | Institute, correct? | | which showed talc particles in the ovaries going |
| 19 | MR. HEGARTY: Objection to the | | back to 1979, a study by Henderson in 1979, |
| 20 | form. | | correct? |
| 21 | THE WITNESS: There were. | 21 | A. Yes. |
| 22 | There were. | 22 | Q. Okay. You didn't have to be you |
| | BY MR. TISI: | | didn't have to be a pathologist to read that |
| 24 | Q. Do you think | 24 | study, right? |
| | Page 443 | | Page 445 |
| 1 | A. But I'd also like to state that in | 1 | MR. HEGARTY: Objection to the |
| l _ | this article, we actually did do an assessment of | 2 | form. |
| 3 | the research that had been published as of this | 3 | THE WITNESS: Yes. |
| 4 | · · · · · · · · · · · · · · · · · · · | 4 | BY MR. TISI: |
| 5 | positive association. | 5 | Q. Okay. You talked about asbestos on |
| 6 | • | | the next page and the fact that it could |
| 7 | A. So to the extent that that | | potentially migrate, correct? |
| 1 | that further studies may prove adequate to raise | 8 | MR. HEGARTY: Objection to |
| | concern at a level sufficient to warrant | 9 | form. |
| | regulatory is not necessary is or even to | 10 | THE WITNESS: Yes. |
| | suggest that we need is to suggest that no further | | |
| | studies are needed because the evidence is not | 12 | Q. Okay. You talked about biologic |
| 1 | there. When, in fact, in the article that I | | plausibility of of asbestos causing ovarian |
| | present in my presentation, I actually showed | | |
| | number of studies, not just mine, that showed | 15 | MR. HEGARTY: Objection to |
| 1 | reasonable consistency and has been has been | 16 | form. |
| 1 | duplicated since then. | 17 | THE WITNESS: I did. |
| 18 | • | | BY MR. TISI: |
| 1 | which is your review article | 19 | Q. Okay. You talked about and you |
| 20 | | | finally came out with and on page 256 on the |
| 21 | Q that came out of this. | | left-hand side. |
| 22 | · · | 22 | A. Uh-huh. |
| 172 | identification as Exhibit P5.) | 23 | Q. You say: |
| 23 | BY MR. TISI: | 24 | "Because the risk of any one outcome |

| | D 446 | | D 440 |
|--|--|--|---|
| 1 | Page 446 is dependent upon both the frequency and length of | 1 | Page 448 |
| 1 | | | time was whether or not they adjusted for these |
| 1 | exposure." You talked shout why you did both of | 3 | confounders, true? A. Yes. |
| 3 | You talked about why you did both of | 3 | |
| | those things, correct? A. Yes. | | Q. In fact, you didn't have to be do |
| 5 | | | a complete comprehensive review of all the medical |
| 6 | Q. Is one of the flaws in the studies | | literature of douching to know that you had to |
| | that you've looked at to date that they either | | adjust for douching, correct? |
| | measured length or frequency but not both | 8 | MR. HEGARTY: Objection to the |
| | together? | 9 | form. |
| 10 | MR. HEGARTY: Objection to | 10 | THE WITNESS: To know that I |
| 11 | form. | 11 | need to determine whether adjusting for |
| 12 | THE WITNESS: I believe | 12 | douching would impact my estimates. |
| 13 | that's a limitation. | | BY MR. TISI: |
| | BY MR. TISI: | 14 | Q. Okay. You talk about in this |
| 15 | Q. Okay. But you tried to do that in | 15 | article in 1995 the recollection of talc |
| 1 | your own studies, correct? | | exposures. |
| 17 | A. Yes. | 17 | Do you see that? |
| 18 | Q. And what did you find in your own | 18 | A. Where are we talking about now? |
| 19 | | 19 | Q. On page 257. |
| 20 | A. We found the dose response | 20 | A. Oh, 257. Where are we? Where are |
| 21 | Q. Okay. | | we now? |
| 22 | A when there was an open genital | 22 | Q. On page 257. |
| - | tract. | 23 | A. Yes. |
| 24 | Q. And, in fact, you put that in your | 24 | Q. The bottom to the next page, |
| | | | |
| ١. | Page 447 | | Page 449 |
| | article here. It says: | | correct? |
| 2 | article here. It says: "There was a sizable increase in | 2 | correct? A. Where it starts "Thus the basic |
| 3 | article here. It says: "There was a sizable increase in risk in women with more than 10,000 applications | 2 3 | correct? A. Where it starts "Thus the basic design"? |
| 2 3 4 | article here. It says: "There was a sizable increase in risk in women with more than 10,000 applications of talc which persisted after multivariate | 2 3 4 | correct? A. Where it starts "Thus the basic design"? Q. On the very bottom. I'm sorry. It |
| 2 3 4 5 | article here. It says: "There was a sizable increase in risk in women with more than 10,000 applications of talc which persisted after multivariate adjustment for parity, education, marital status, | 2 3 4 5 | correct? A. Where it starts "Thus the basic design"? Q. On the very bottom. I'm sorry. It says "Recollection of Talc Exposure." |
| 2 3 4 5 6 | article here. It says: "There was a sizable increase in risk in women with more than 10,000 applications of talc which persisted after multivariate adjustment for parity, education, marital status, douching, weight, and use of sanitary napkins." | 2 3 4 5 6 | correct? A. Where it starts "Thus the basic design"? Q. On the very bottom. I'm sorry. It says "Recollection of Talc Exposure." On the bottom right-hand side. |
| 2 3 4 5 6 7 | article here. It says: "There was a sizable increase in risk in women with more than 10,000 applications of talc which persisted after multivariate adjustment for parity, education, marital status, douching, weight, and use of sanitary napkins." Do you see that? | 2 3 4 5 6 7 | correct? A. Where it starts "Thus the basic design"? Q. On the very bottom. I'm sorry. It says "Recollection of Talc Exposure." On the bottom right-hand side. A. Oh, I'm sorry. Got it. |
| 2 3 4 5 6 7 8 | article here. It says: "There was a sizable increase in risk in women with more than 10,000 applications of talc which persisted after multivariate adjustment for parity, education, marital status, douching, weight, and use of sanitary napkins." Do you see that? A. Yes, I do. | 2 3 4 5 6 7 8 | correct? A. Where it starts "Thus the basic design"? Q. On the very bottom. I'm sorry. It says "Recollection of Talc Exposure." On the bottom right-hand side. A. Oh, I'm sorry. Got it. Q. On page 257 going on to the next |
| 2 3 4 5 6 7 8 9 | article here. It says: "There was a sizable increase in risk in women with more than 10,000 applications of talc which persisted after multivariate adjustment for parity, education, marital status, douching, weight, and use of sanitary napkins." Do you see that? A. Yes, I do. Q. Now, counsel asked you whether or | 2 3 4 5 6 7 8 9 | correct? A. Where it starts "Thus the basic design"? Q. On the very bottom. I'm sorry. It says "Recollection of Talc Exposure." On the bottom right-hand side. A. Oh, I'm sorry. Got it. Q. On page 257 going on to the next page. |
| 2 3 4 5 6 7 8 9 10 | article here. It says: "There was a sizable increase in risk in women with more than 10,000 applications of talc which persisted after multivariate adjustment for parity, education, marital status, douching, weight, and use of sanitary napkins." Do you see that? A. Yes, I do. Q. Now, counsel asked you whether or not you looked at the literature relating to | 2 3 4 5 6 7 8 9 | correct? A. Where it starts "Thus the basic design"? Q. On the very bottom. I'm sorry. It says "Recollection of Talc Exposure." On the bottom right-hand side. A. Oh, I'm sorry. Got it. Q. On page 257 going on to the next page. A. Yes. Yes, yes, yes. I'm there. |
| 2 3 4 5 6 7 8 9 10 11 | article here. It says: "There was a sizable increase in risk in women with more than 10,000 applications of talc which persisted after multivariate adjustment for parity, education, marital status, douching, weight, and use of sanitary napkins." Do you see that? A. Yes, I do. Q. Now, counsel asked you whether or not you looked at the literature relating to things like douching, weight, and the risks of | 2 3 4 5 6 7 8 9 10 11 | correct? A. Where it starts "Thus the basic design"? Q. On the very bottom. I'm sorry. It says "Recollection of Talc Exposure." On the bottom right-hand side. A. Oh, I'm sorry. Got it. Q. On page 257 going on to the next page. A. Yes. Yes, yes, yes. I'm there. I'm there. Yes. |
| 2 3 4 5 6 7 8 9 10 11 12 | article here. It says: "There was a sizable increase in risk in women with more than 10,000 applications of talc which persisted after multivariate adjustment for parity, education, marital status, douching, weight, and use of sanitary napkins." Do you see that? A. Yes, I do. Q. Now, counsel asked you whether or not you looked at the literature relating to things like douching, weight, and the risks of ovarian cancer, true? | 2 3 4 5 6 7 8 9 10 11 12 | correct? A. Where it starts "Thus the basic design"? Q. On the very bottom. I'm sorry. It says "Recollection of Talc Exposure." On the bottom right-hand side. A. Oh, I'm sorry. Got it. Q. On page 257 going on to the next page. A. Yes. Yes, yes, yes. I'm there. I'm there. Yes. Q. Now, you offer the opinion that |
| 2 3 4 5 6 7 8 9 10 11 12 13 | article here. It says: "There was a sizable increase in risk in women with more than 10,000 applications of talc which persisted after multivariate adjustment for parity, education, marital status, douching, weight, and use of sanitary napkins." Do you see that? A. Yes, I do. Q. Now, counsel asked you whether or not you looked at the literature relating to things like douching, weight, and the risks of ovarian cancer, true? MR. HEGARTY: Objection to the | 2 3 4 5 6 7 8 9 10 11 12 13 | correct? A. Where it starts "Thus the basic design"? Q. On the very bottom. I'm sorry. It says "Recollection of Talc Exposure." On the bottom right-hand side. A. Oh, I'm sorry. Got it. Q. On page 257 going on to the next page. A. Yes. Yes, yes, yes. I'm there. I'm there. Yes. Q. Now, you offer the opinion that today that misclassification because of recall |
| 2 3 4 5 6 7 8 9 10 11 12 13 14 | article here. It says: "There was a sizable increase in risk in women with more than 10,000 applications of talc which persisted after multivariate adjustment for parity, education, marital status, douching, weight, and use of sanitary napkins." Do you see that? A. Yes, I do. Q. Now, counsel asked you whether or not you looked at the literature relating to things like douching, weight, and the risks of ovarian cancer, true? MR. HEGARTY: Objection to the form. | 2 3 4 5 6 7 8 9 10 11 12 13 14 | correct? A. Where it starts "Thus the basic design"? Q. On the very bottom. I'm sorry. It says "Recollection of Talc Exposure." On the bottom right-hand side. A. Oh, I'm sorry. Got it. Q. On page 257 going on to the next page. A. Yes. Yes, yes, yes. I'm there. I'm there. Yes. Q. Now, you offer the opinion that today that misclassification because of recall bias differentially in the case-control studies |
| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 | article here. It says: "There was a sizable increase in risk in women with more than 10,000 applications of talc which persisted after multivariate adjustment for parity, education, marital status, douching, weight, and use of sanitary napkins." Do you see that? A. Yes, I do. Q. Now, counsel asked you whether or not you looked at the literature relating to things like douching, weight, and the risks of ovarian cancer, true? MR. HEGARTY: Objection to the form. THE WITNESS: In in | 2 3 4 5 6 7 8 9 10 11 12 13 14 15 | correct? A. Where it starts "Thus the basic design"? Q. On the very bottom. I'm sorry. It says "Recollection of Talc Exposure." On the bottom right-hand side. A. Oh, I'm sorry. Got it. Q. On page 257 going on to the next page. A. Yes. Yes, yes, yes. I'm there. I'm there. Yes. Q. Now, you offer the opinion that today that misclassification because of recall bias differentially in the case-control studies might be a problem if it was not a routine or |
| 2 3 4 5 6 7 8 9 10 11 12 13 14 | article here. It says: "There was a sizable increase in risk in women with more than 10,000 applications of talc which persisted after multivariate adjustment for parity, education, marital status, douching, weight, and use of sanitary napkins." Do you see that? A. Yes, I do. Q. Now, counsel asked you whether or not you looked at the literature relating to things like douching, weight, and the risks of ovarian cancer, true? MR. HEGARTY: Objection to the form. THE WITNESS: In in preparation of the report that I did? | 2 3 4 5 6 7 8 9 10 11 12 13 14 15 | correct? A. Where it starts "Thus the basic design"? Q. On the very bottom. I'm sorry. It says "Recollection of Talc Exposure." On the bottom right-hand side. A. Oh, I'm sorry. Got it. Q. On page 257 going on to the next page. A. Yes. Yes, yes, yes. I'm there. I'm there. Yes. Q. Now, you offer the opinion that today that misclassification because of recall bias differentially in the case-control studies |
| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 | article here. It says: "There was a sizable increase in risk in women with more than 10,000 applications of talc which persisted after multivariate adjustment for parity, education, marital status, douching, weight, and use of sanitary napkins." Do you see that? A. Yes, I do. Q. Now, counsel asked you whether or not you looked at the literature relating to things like douching, weight, and the risks of ovarian cancer, true? MR. HEGARTY: Objection to the form. THE WITNESS: In in preparation of the report that I did? BY MR. TISI: | 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 | A. Where it starts "Thus the basic design"? Q. On the very bottom. I'm sorry. It says "Recollection of Talc Exposure." On the bottom right-hand side. A. Oh, I'm sorry. Got it. Q. On page 257 going on to the next page. A. Yes. Yes, yes, yes. I'm there. I'm there. Yes. Q. Now, you offer the opinion that today that misclassification because of recall bias differentially in the case-control studies might be a problem if it was not a routine or habit of a woman, but if something is routine, it would be not as much of a problem, correct? |
| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 | article here. It says: "There was a sizable increase in risk in women with more than 10,000 applications of talc which persisted after multivariate adjustment for parity, education, marital status, douching, weight, and use of sanitary napkins." Do you see that? A. Yes, I do. Q. Now, counsel asked you whether or not you looked at the literature relating to things like douching, weight, and the risks of ovarian cancer, true? MR. HEGARTY: Objection to the form. THE WITNESS: In in preparation of the report that I did? BY MR. TISI: Q. Right. | 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 | correct? A. Where it starts "Thus the basic design"? Q. On the very bottom. I'm sorry. It says "Recollection of Talc Exposure." On the bottom right-hand side. A. Oh, I'm sorry. Got it. Q. On page 257 going on to the next page. A. Yes. Yes, yes, yes. I'm there. I'm there. Yes. Q. Now, you offer the opinion that today that misclassification because of recall bias differentially in the case-control studies might be a problem if it was not a routine or habit of a woman, but if something is routine, it would be not as much of a problem, correct? A. Yes. |
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| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 | "There was a sizable increase in risk in women with more than 10,000 applications of talc which persisted after multivariate adjustment for parity, education, marital status, douching, weight, and use of sanitary napkins." Do you see that? A. Yes, I do. Q. Now, counsel asked you whether or not you looked at the literature relating to things like douching, weight, and the risks of ovarian cancer, true? MR. HEGARTY: Objection to the form. THE WITNESS: In in preparation of the report that I did? BY MR. TISI: Q. Right. A. No, I didn't do that for preparation of the report. I obviously did that in deciding | 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 | correct? A. Where it starts "Thus the basic design"? Q. On the very bottom. I'm sorry. It says "Recollection of Talc Exposure." On the bottom right-hand side. A. Oh, I'm sorry. Got it. Q. On page 257 going on to the next page. A. Yes. Yes, yes, yes. I'm there. I'm there. Yes. Q. Now, you offer the opinion that today that misclassification because of recall bias differentially in the case-control studies might be a problem if it was not a routine or habit of a woman, but if something is routine, it would be not as much of a problem, correct? A. Yes. MR. HEGARTY: Objection to the form. |
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| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 | "There was a sizable increase in risk in women with more than 10,000 applications of talc which persisted after multivariate adjustment for parity, education, marital status, douching, weight, and use of sanitary napkins." Do you see that? A. Yes, I do. Q. Now, counsel asked you whether or not you looked at the literature relating to things like douching, weight, and the risks of ovarian cancer, true? MR. HEGARTY: Objection to the form. THE WITNESS: In in preparation of the report that I did? BY MR. TISI: Q. Right. A. No, I didn't do that for preparation of the report. I obviously did that in deciding what potential covariates we should adjust for in our analyses in this, in the 1992 paper. Q. In fact, one of the things you | 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 | correct? A. Where it starts "Thus the basic design"? Q. On the very bottom. I'm sorry. It says "Recollection of Talc Exposure." On the bottom right-hand side. A. Oh, I'm sorry. Got it. Q. On page 257 going on to the next page. A. Yes. Yes, yes, yes. I'm there. I'm there. Yes. Q. Now, you offer the opinion that today that misclassification because of recall bias differentially in the case-control studies might be a problem if it was not a routine or habit of a woman, but if something is routine, it would be not as much of a problem, correct? A. Yes. MR. HEGARTY: Objection to the form. BY MR. TISI: Q. Is that something you wrote right here at the bottom of page 250 excuse me 258 |
| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 | "There was a sizable increase in risk in women with more than 10,000 applications of talc which persisted after multivariate adjustment for parity, education, marital status, douching, weight, and use of sanitary napkins." Do you see that? A. Yes, I do. Q. Now, counsel asked you whether or not you looked at the literature relating to things like douching, weight, and the risks of ovarian cancer, true? MR. HEGARTY: Objection to the form. THE WITNESS: In in preparation of the report that I did? BY MR. TISI: Q. Right. A. No, I didn't do that for preparation of the report. I obviously did that in deciding what potential covariates we should adjust for in our analyses in this, in the 1992 paper. | 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 | correct? A. Where it starts "Thus the basic design"? Q. On the very bottom. I'm sorry. It says "Recollection of Talc Exposure." On the bottom right-hand side. A. Oh, I'm sorry. Got it. Q. On page 257 going on to the next page. A. Yes. Yes, yes, yes. I'm there. I'm there. Yes. Q. Now, you offer the opinion that today that misclassification because of recall bias differentially in the case-control studies might be a problem if it was not a routine or habit of a woman, but if something is routine, it would be not as much of a problem, correct? A. Yes. MR. HEGARTY: Objection to the form. BY MR. TISI: Q. Is that something you wrote right |

| Page 450 1 "Differential misclassification and | Page 452 |
|---|---|
| 2 random error are most likely to occur if the | 2 Q. So the point is here do you feel |
| 3 question is too long or too vague and if the | 3 that the if anybody were to first of all, |
| 4 behavior itself is intermittent and trivial." | 4 Dr. Carr was not an employee of the FDA, the |
| 5 A. Correct. | 5 person who took these minutes, correct? |
| 6 Q. Okay. Do you see that? | 6 MR. HEGARTY: Objection to the |
| 7 A. Yes. | 7 form. |
| 8 Q. Okay. And you also noted on the top | 8 THE WITNESS: I have no idea |
| 9 part that the risk | 9 who Dr I don't even know if it's |
| 10 A. Where are you referring to now? | 10 Dr. Carr. I don't know who that person |
| 11 Q. In the chart, Table 3. | 11 was. |
| 12 A. Oh, Table 3, yes. | 12 BY MR. TISI: |
| 13 Q. That people with prior to tubal | 13 Q. Was there anything in the |
| 14 ligation, hysterectomy, and during ovulatory | 14 presentations that were made that changed your |
| 15 periods only, the risk for greater than 10,000 | 15 view that women ought to be that risks that |
| 16 applications was 2.8. | 16 the risks ought to be mitigated based upon at |
| 17 Do you see that? | 17 least what's available 30, 40 years ago |
| 18 A. Yes. | 18 MR. HEGARTY: Objection. |
| 19 Q. Okay. Now, at the summary of your | 19 BY MR. TISI: |
| 20 article, you indicated what you thought was the | 20 Q after going to this meeting at |
| 21 range of relative risks based upon the literature | 21 the FDA? |
| 22 existed at that time, correct? | 22 MR. HEGARTY: Objection to the |
| 23 A. Yes. | 23 form. |
| 24 MR. HEGARTY: Objection to the | 24 THE WITNESS: Can you repeat |
| | |
| Page 451 | Page 453 1 the question? I'm sorry. |
| 2 BY MR. TISI: | 2 BY MR. TISI: |
| 3 Q. You mentioned several times today | 3 Q. Yeah. |
| 4 that you thought that risk was between 1.0, 1.8, | 4 Is there anything that you heard at |
| 5 correct? | 5 that meeting that changed your view expressed |
| 6 A. Yes. | 6 your 1992 letter |
| 7 MR. HEGARTY: Objection to the | 7 A. Article. |
| 8 form. | 8 Q article that women should not use |
| | |
| 9 BY MR. TISI: | |
| 9 BY MR. TISI: 10 O. You wrote that back in 1995. | 9 talcum powder products because of the risk of |
| 10 Q. You wrote that back in 1995, | 9 talcum powder products because of the risk of 10 cancer? |
| 10 Q. You wrote that back in 1995, 11 correct, in this article? | 9 talcum powder products because of the risk of 10 cancer? 11 A. There was nothing |
| 10 Q. You wrote that back in 1995, 11 correct, in this article? 12 MR. HEGARTY: Objection to the | 9 talcum powder products because of the risk of 10 cancer? 11 A. There was nothing 12 MR. HEGARTY: Objection to |
| 10 Q. You wrote that back in 1995, 11 correct, in this article? 12 MR. HEGARTY: Objection to the 13 form. | 9 talcum powder products because of the risk of 10 cancer? 11 A. There was nothing 12 MR. HEGARTY: Objection to 13 form. |
| 10 Q. You wrote that back in 1995, 11 correct, in this article? 12 MR. HEGARTY: Objection to the 13 form. 14 THE WITNESS: And I believe I | 9 talcum powder products because of the risk of 10 cancer? 11 A. There was nothing 12 MR. HEGARTY: Objection to 13 form. 14 THE WITNESS: that changed |
| 10 Q. You wrote that back in 1995, 11 correct, in this article? 12 MR. HEGARTY: Objection to the 13 form. 14 THE WITNESS: And I believe I 15 presented it at the at the conference | 9 talcum powder products because of the risk of 10 cancer? 11 A. There was nothing 12 MR. HEGARTY: Objection to 13 form. 14 THE WITNESS: that changed 15 my view that women should curtail, if not |
| 10 Q. You wrote that back in 1995, 11 correct, in this article? 12 MR. HEGARTY: Objection to the 13 form. 14 THE WITNESS: And I believe I 15 presented it at the at the conference 16 as well. | 9 talcum powder products because of the risk of 10 cancer? 11 A. There was nothing 12 MR. HEGARTY: Objection to 13 form. 14 THE WITNESS: that changed 15 my view that women should curtail, if not 16 completely abstain from, perineal |
| 10 Q. You wrote that back in 1995, 11 correct, in this article? 12 MR. HEGARTY: Objection to the 13 form. 14 THE WITNESS: And I believe I 15 presented it at the at the conference 16 as well. 17 BY MR. TISI: | 9 talcum powder products because of the risk of 10 cancer? 11 A. There was nothing 12 MR. HEGARTY: Objection to 13 form. 14 THE WITNESS: that changed 15 my view that women should curtail, if not 16 completely abstain from, perineal 17 application of talcum powder. |
| 10 Q. You wrote that back in 1995, 11 correct, in this article? 12 MR. HEGARTY: Objection to the 13 form. 14 THE WITNESS: And I believe I 15 presented it at the at the conference 16 as well. 17 BY MR. TISI: 18 Q. That wasn't in the summary of the | 9 talcum powder products because of the risk of 10 cancer? 11 A. There was nothing 12 MR. HEGARTY: Objection to 13 form. 14 THE WITNESS: that changed 15 my view that women should curtail, if not 16 completely abstain from, perineal 17 application of talcum powder. 18 BY MR. TISI: |
| 10 Q. You wrote that back in 1995, 11 correct, in this article? 12 MR. HEGARTY: Objection to the 13 form. 14 THE WITNESS: And I believe I 15 presented it at the at the conference 16 as well. 17 BY MR. TISI: 18 Q. That wasn't in the summary of the 19 of the conference, was it? | 9 talcum powder products because of the risk of 10 cancer? 11 A. There was nothing 12 MR. HEGARTY: Objection to 13 form. 14 THE WITNESS: that changed 15 my view that women should curtail, if not 16 completely abstain from, perineal 17 application of talcum powder. 18 BY MR. TISI: 19 Q. In fact, you reiterated that in your |
| 10 Q. You wrote that back in 1995, 11 correct, in this article? 12 MR. HEGARTY: Objection to the 13 form. 14 THE WITNESS: And I believe I 15 presented it at the at the conference 16 as well. 17 BY MR. TISI: 18 Q. That wasn't in the summary of the 19 of the conference, was it? 20 A. No, but it was in the minutes of | 9 talcum powder products because of the risk of 10 cancer? 11 A. There was nothing 12 MR. HEGARTY: Objection to 13 form. 14 THE WITNESS: that changed 15 my view that women should curtail, if not 16 completely abstain from, perineal 17 application of talcum powder. 18 BY MR. TISI: 19 Q. In fact, you reiterated that in your 20 1999 article, correct? |
| 10 Q. You wrote that back in 1995, 11 correct, in this article? 12 MR. HEGARTY: Objection to the 13 form. 14 THE WITNESS: And I believe I 15 presented it at the at the conference 16 as well. 17 BY MR. TISI: 18 Q. That wasn't in the summary of the 19 of the conference, was it? 20 A. No, but it was in the minutes of 21 the the what do they call it? Minutes of | 9 talcum powder products because of the risk of 10 cancer? 11 A. There was nothing 12 MR. HEGARTY: Objection to 13 form. 14 THE WITNESS: that changed 15 my view that women should curtail, if not 16 completely abstain from, perineal 17 application of talcum powder. 18 BY MR. TISI: 19 Q. In fact, you reiterated that in your 20 1999 article, correct? 21 MR. HEGARTY: Objection to |
| 10 Q. You wrote that back in 1995, 11 correct, in this article? 12 MR. HEGARTY: Objection to the 13 form. 14 THE WITNESS: And I believe I 15 presented it at the at the conference 16 as well. 17 BY MR. TISI: 18 Q. That wasn't in the summary of the 19 of the conference, was it? 20 A. No, but it was in the minutes of 21 the the what do they call it? Minutes of 22 the meeting. | 9 talcum powder products because of the risk of 10 cancer? 11 A. There was nothing 12 MR. HEGARTY: Objection to 13 form. 14 THE WITNESS: that changed 15 my view that women should curtail, if not 16 completely abstain from, perineal 17 application of talcum powder. 18 BY MR. TISI: 19 Q. In fact, you reiterated that in your 20 1999 article, correct? 21 MR. HEGARTY: Objection to 22 form. |
| 10 Q. You wrote that back in 1995, 11 correct, in this article? 12 MR. HEGARTY: Objection to the 13 form. 14 THE WITNESS: And I believe I 15 presented it at the at the conference 16 as well. 17 BY MR. TISI: 18 Q. That wasn't in the summary of the 19 of the conference, was it? 20 A. No, but it was in the minutes of 21 the the what do they call it? Minutes of | 9 talcum powder products because of the risk of 10 cancer? 11 A. There was nothing 12 MR. HEGARTY: Objection to 13 form. 14 THE WITNESS: that changed 15 my view that women should curtail, if not 16 completely abstain from, perineal 17 application of talcum powder. 18 BY MR. TISI: 19 Q. In fact, you reiterated that in your 20 1999 article, correct? 21 MR. HEGARTY: Objection to |

| Page 454 | Page 456 |
|--|--|
| 1 you that article, Exhibit Number 5. | 1 A. It means that "Excludes applications |
| 2 MR. HEGARTY: I have Exhibit | 2 following hysterectomy or tubal ligation and |
| 3 Number 6, P6. | 3 applications during pregnancy and periods of oral |
| 4 MR. TISI: Oh. Exhibit | 4 contraceptive use." |
| 5 Number 6. I'm sorry. | 5 Q. Okay. Why did you do that? |
| 6 MR. HEGARTY: I have the last | 6 A. Because women would not necessarily |
| 7 article you designated as P5. | 7 be ovulating and the idea the potential |
| 8 (Document marked for | 8 possibilities that with the talc migrating during |
| 9 identification as Exhibit P6.) | 9 ovulatory times, the talc particulates have the |
| 10 BY MR. TISI: | 10 opportunity to embed into the inclusion cysts |
| 11 Q. Okay. This is P6. It's entitled | 11 after ovulation. |
| 12 "Genital Talc Exposure and Risk of Ovarian | 12 Q. Okay. And so this was a recognition |
| 13 Cancer." This is the 1990 article by Dr. Cramer. | 13 that there was was this a recognition that |
| Do you see that? | 14 there was a biologically plausible mechanism that |
| 15 A. Yes. | 15 talc applied perineally could could travel up |
| 16 Q. Now, you were asked several | 16 the up the genital tract, reach the ovaries, |
| 17 questions about whether Dr. Cramer was an expert | 17 and you wanted to test that hypothesis in this |
| 18 for plaintiffs. | 18 study, correct? |
| 19 You know that, right? | 19 MR. HEGARTY: Objection to the |
| 20 A. Yes. | 20 form. |
| 21 Q. Again, I'm going to represent to you | 21 THE WITNESS: Yes. |
| 22 that the first case for ovarian cancer had not | 22 BY MR. TISI: |
| 23 even been filed until at least 10, 15 years after | 23 Q. Okay. And when you looked at |
| 24 this article was published. | 24 applications with less than 3,000 applications, |
| Page 455 | Page 457 |
| - 100 | |
| 1 Do you have any reason to believe | 1 what did you see? |
| , , | 1 what did you see? 2 A. We saw the highest adjusted odds |
| 2 that Dr. Cramer was an expert or consultant in | 2 A. We saw the highest adjusted odds |
| | 2 A. We saw the highest adjusted odds 3 ratio being in those that had greater than 10,000 |
| 2 that Dr. Cramer was an expert or consultant in3 talc litigation at the time you wrote this4 article? | 2 A. We saw the highest adjusted odds 3 ratio being in those that had greater than 10,000 |
| 2 that Dr. Cramer was an expert or consultant in 3 talc litigation at the time you wrote this 4 article? | 2 A. We saw the highest adjusted odds 3 ratio being in those that had greater than 10,000 4 applications when limiting this exposure 5 assessment. |
| 2 that Dr. Cramer was an expert or consultant in 3 talc litigation at the time you wrote this 4 article? 5 MR. HEGARTY: Objection to the 6 form. | 2 A. We saw the highest adjusted odds 3 ratio being in those that had greater than 10,000 4 applications when limiting this exposure 5 assessment. 6 Q. Okay. Did you see a dose response |
| 2 that Dr. Cramer was an expert or consultant in 3 talc litigation at the time you wrote this 4 article? 5 MR. HEGARTY: Objection to the | 2 A. We saw the highest adjusted odds 3 ratio being in those that had greater than 10,000 4 applications when limiting this exposure 5 assessment. 6 Q. Okay. Did you see a dose response 7 when you compared 3,000, 3,000 to 10,000, and |
| 2 that Dr. Cramer was an expert or consultant in 3 talc litigation at the time you wrote this 4 article? 5 MR. HEGARTY: Objection to the 6 form. 7 THE WITNESS: No. 8 BY MR. TISI: | 2 A. We saw the highest adjusted odds 3 ratio being in those that had greater than 10,000 4 applications when limiting this exposure 5 assessment. 6 Q. Okay. Did you see a dose response 7 when you compared 3,000, 3,000 to 10,000, and |
| 2 that Dr. Cramer was an expert or consultant in 3 talc litigation at the time you wrote this 4 article? 5 MR. HEGARTY: Objection to the 6 form. 7 THE WITNESS: No. 8 BY MR. TISI: 9 Q. Okay. Now, in this article, you | 2 A. We saw the highest adjusted odds 3 ratio being in those that had greater than 10,000 4 applications when limiting this exposure 5 assessment. 6 Q. Okay. Did you see a dose response 7 when you compared 3,000, 3,000 to 10,000, and 8 greater than 10,000? 9 A. The risks |
| 2 that Dr. Cramer was an expert or consultant in 3 talc litigation at the time you wrote this 4 article? 5 MR. HEGARTY: Objection to the 6 form. 7 THE WITNESS: No. 8 BY MR. TISI: 9 Q. Okay. Now, in this article, you 10 concluded that there was, in fact, a dose response | 2 A. We saw the highest adjusted odds 3 ratio being in those that had greater than 10,000 4 applications when limiting this exposure 5 assessment. 6 Q. Okay. Did you see a dose response 7 when you compared 3,000, 3,000 to 10,000, and 8 greater than 10,000? 9 A. The risks |
| 2 that Dr. Cramer was an expert or consultant in 3 talc litigation at the time you wrote this 4 article? 5 MR. HEGARTY: Objection to the 6 form. 7 THE WITNESS: No. 8 BY MR. TISI: 9 Q. Okay. Now, in this article, you 10 concluded that there was, in fact, a dose response 11 when considering all application for women | 2 A. We saw the highest adjusted odds 3 ratio being in those that had greater than 10,000 4 applications when limiting this exposure 5 assessment. 6 Q. Okay. Did you see a dose response 7 when you compared 3,000, 3,000 to 10,000, and 8 greater than 10,000? 9 A. The risks 10 MR. HEGARTY: Objection to the |
| 2 that Dr. Cramer was an expert or consultant in 3 talc litigation at the time you wrote this 4 article? 5 MR. HEGARTY: Objection to the 6 form. 7 THE WITNESS: No. 8 BY MR. TISI: 9 Q. Okay. Now, in this article, you 10 concluded that there was, in fact, a dose response 11 when considering all application for women 12 particularly with patent tubes, correct? | 2 A. We saw the highest adjusted odds 3 ratio being in those that had greater than 10,000 4 applications when limiting this exposure 5 assessment. 6 Q. Okay. Did you see a dose response 7 when you compared 3,000, 3,000 to 10,000, and 8 greater than 10,000? 9 A. The risks 10 MR. HEGARTY: Objection to the 11 form. |
| 2 that Dr. Cramer was an expert or consultant in 3 talc litigation at the time you wrote this 4 article? 5 MR. HEGARTY: Objection to the 6 form. 7 THE WITNESS: No. 8 BY MR. TISI: 9 Q. Okay. Now, in this article, you 10 concluded that there was, in fact, a dose response 11 when considering all application for women 12 particularly with patent tubes, correct? 13 MR. HEGARTY: Objection to the | 2 A. We saw the highest adjusted odds 3 ratio being in those that had greater than 10,000 4 applications when limiting this exposure 5 assessment. 6 Q. Okay. Did you see a dose response 7 when you compared 3,000, 3,000 to 10,000, and 8 greater than 10,000? 9 A. The risks 10 MR. HEGARTY: Objection to the 11 form. 12 THE WITNESS: The risks went 13 from 1.54 to 1.72 to 1.8. |
| 2 that Dr. Cramer was an expert or consultant in 3 talc litigation at the time you wrote this 4 article? 5 MR. HEGARTY: Objection to the 6 form. 7 THE WITNESS: No. 8 BY MR. TISI: 9 Q. Okay. Now, in this article, you 10 concluded that there was, in fact, a dose response 11 when considering all application for women 12 particularly with patent tubes, correct? 13 MR. HEGARTY: Objection to the 14 form. | 2 A. We saw the highest adjusted odds 3 ratio being in those that had greater than 10,000 4 applications when limiting this exposure 5 assessment. 6 Q. Okay. Did you see a dose response 7 when you compared 3,000, 3,000 to 10,000, and 8 greater than 10,000? 9 A. The risks 10 MR. HEGARTY: Objection to the 11 form. 12 THE WITNESS: The risks went 13 from 1.54 to 1.72 to 1.8. 14 BY MR. TISI: |
| 2 that Dr. Cramer was an expert or consultant in 3 talc litigation at the time you wrote this 4 article? 5 MR. HEGARTY: Objection to the 6 form. 7 THE WITNESS: No. 8 BY MR. TISI: 9 Q. Okay. Now, in this article, you 10 concluded that there was, in fact, a dose response 11 when considering all application for women 12 particularly with patent tubes, correct? 13 MR. HEGARTY: Objection to the | 2 A. We saw the highest adjusted odds 3 ratio being in those that had greater than 10,000 4 applications when limiting this exposure 5 assessment. 6 Q. Okay. Did you see a dose response 7 when you compared 3,000, 3,000 to 10,000, and 8 greater than 10,000? 9 A. The risks 10 MR. HEGARTY: Objection to the 11 form. 12 THE WITNESS: The risks went 13 from 1.54 to 1.72 to 1.8. 14 BY MR. TISI: 15 Q. Were they all statistically |
| 2 that Dr. Cramer was an expert or consultant in 3 talc litigation at the time you wrote this 4 article? 5 MR. HEGARTY: Objection to the 6 form. 7 THE WITNESS: No. 8 BY MR. TISI: 9 Q. Okay. Now, in this article, you 10 concluded that there was, in fact, a dose response 11 when considering all application for women 12 particularly with patent tubes, correct? 13 MR. HEGARTY: Objection to the 14 form. 15 THE WITNESS: That is | 2 A. We saw the highest adjusted odds 3 ratio being in those that had greater than 10,000 4 applications when limiting this exposure 5 assessment. 6 Q. Okay. Did you see a dose response 7 when you compared 3,000, 3,000 to 10,000, and 8 greater than 10,000? 9 A. The risks 10 MR. HEGARTY: Objection to the 11 form. 12 THE WITNESS: The risks went 13 from 1.54 to 1.72 to 1.8. 14 BY MR. TISI: |
| 2 that Dr. Cramer was an expert or consultant in 3 talc litigation at the time you wrote this 4 article? 5 MR. HEGARTY: Objection to the 6 form. 7 THE WITNESS: No. 8 BY MR. TISI: 9 Q. Okay. Now, in this article, you 10 concluded that there was, in fact, a dose response 11 when considering all application for women 12 particularly with patent tubes, correct? 13 MR. HEGARTY: Objection to the 14 form. 15 THE WITNESS: That is 16 correct. 17 BY MR. TISI: | 2 A. We saw the highest adjusted odds 3 ratio being in those that had greater than 10,000 4 applications when limiting this exposure 5 assessment. 6 Q. Okay. Did you see a dose response 7 when you compared 3,000, 3,000 to 10,000, and 8 greater than 10,000? 9 A. The risks 10 MR. HEGARTY: Objection to the 11 form. 12 THE WITNESS: The risks went 13 from 1.54 to 1.72 to 1.8. 14 BY MR. TISI: 15 Q. Were they all statistically 16 significant? |
| 2 that Dr. Cramer was an expert or consultant in 3 talc litigation at the time you wrote this 4 article? 5 MR. HEGARTY: Objection to the 6 form. 7 THE WITNESS: No. 8 BY MR. TISI: 9 Q. Okay. Now, in this article, you 10 concluded that there was, in fact, a dose response 11 when considering all application for women 12 particularly with patent tubes, correct? 13 MR. HEGARTY: Objection to the 14 form. 15 THE WITNESS: That is 16 correct. 17 BY MR. TISI: 18 Q. Would you go to page Table III, | 2 A. We saw the highest adjusted odds 3 ratio being in those that had greater than 10,000 4 applications when limiting this exposure 5 assessment. 6 Q. Okay. Did you see a dose response 7 when you compared 3,000, 3,000 to 10,000, and 8 greater than 10,000? 9 A. The risks 10 MR. HEGARTY: Objection to the 11 form. 12 THE WITNESS: The risks went 13 from 1.54 to 1.72 to 1.8. 14 BY MR. TISI: 15 Q. Were they all statistically 16 significant? 17 A. The confidence intervals did not 18 included 1. |
| 2 that Dr. Cramer was an expert or consultant in 3 talc litigation at the time you wrote this 4 article? 5 MR. HEGARTY: Objection to the 6 form. 7 THE WITNESS: No. 8 BY MR. TISI: 9 Q. Okay. Now, in this article, you 10 concluded that there was, in fact, a dose response 11 when considering all application for women 12 particularly with patent tubes, correct? 13 MR. HEGARTY: Objection to the 14 form. 15 THE WITNESS: That is 16 correct. 17 BY MR. TISI: 18 Q. Would you go to page Table III, 19 please? | 2 A. We saw the highest adjusted odds 3 ratio being in those that had greater than 10,000 4 applications when limiting this exposure 5 assessment. 6 Q. Okay. Did you see a dose response 7 when you compared 3,000, 3,000 to 10,000, and 8 greater than 10,000? 9 A. The risks 10 MR. HEGARTY: Objection to the 11 form. 12 THE WITNESS: The risks went 13 from 1.54 to 1.72 to 1.8. 14 BY MR. TISI: 15 Q. Were they all statistically 16 significant? 17 A. The confidence intervals did not 18 included 1. 19 Q. Okay. |
| 2 that Dr. Cramer was an expert or consultant in 3 talc litigation at the time you wrote this 4 article? 5 MR. HEGARTY: Objection to the 6 form. 7 THE WITNESS: No. 8 BY MR. TISI: 9 Q. Okay. Now, in this article, you 10 concluded that there was, in fact, a dose response 11 when considering all application for women 12 particularly with patent tubes, correct? 13 MR. HEGARTY: Objection to the 14 form. 15 THE WITNESS: That is 16 correct. 17 BY MR. TISI: 18 Q. Would you go to page Table III, 19 please? 20 A. Uh-huh. | 2 A. We saw the highest adjusted odds 3 ratio being in those that had greater than 10,000 4 applications when limiting this exposure 5 assessment. 6 Q. Okay. Did you see a dose response 7 when you compared 3,000, 3,000 to 10,000, and 8 greater than 10,000? 9 A. The risks 10 MR. HEGARTY: Objection to the 11 form. 12 THE WITNESS: The risks went 13 from 1.54 to 1.72 to 1.8. 14 BY MR. TISI: 15 Q. Were they all statistically 16 significant? 17 A. The confidence intervals did not 18 included 1. 19 Q. Okay. 20 A. Not yes, included 1 in all of |
| 2 that Dr. Cramer was an expert or consultant in 3 talc litigation at the time you wrote this 4 article? 5 MR. HEGARTY: Objection to the 6 form. 7 THE WITNESS: No. 8 BY MR. TISI: 9 Q. Okay. Now, in this article, you 10 concluded that there was, in fact, a dose response 11 when considering all application for women 12 particularly with patent tubes, correct? 13 MR. HEGARTY: Objection to the 14 form. 15 THE WITNESS: That is 16 correct. 17 BY MR. TISI: 18 Q. Would you go to page Table III, 19 please? 20 A. Uh-huh. 21 Q. It says when you censured patients. | 2 A. We saw the highest adjusted odds 3 ratio being in those that had greater than 10,000 4 applications when limiting this exposure 5 assessment. 6 Q. Okay. Did you see a dose response 7 when you compared 3,000, 3,000 to 10,000, and 8 greater than 10,000? 9 A. The risks 10 MR. HEGARTY: Objection to the 11 form. 12 THE WITNESS: The risks went 13 from 1.54 to 1.72 to 1.8. 14 BY MR. TISI: 15 Q. Were they all statistically 16 significant? 17 A. The confidence intervals did not 18 included 1. 19 Q. Okay. 20 A. Not yes, included 1 in all of 21 them. |
| 2 that Dr. Cramer was an expert or consultant in 3 talc litigation at the time you wrote this 4 article? 5 MR. HEGARTY: Objection to the 6 form. 7 THE WITNESS: No. 8 BY MR. TISI: 9 Q. Okay. Now, in this article, you 10 concluded that there was, in fact, a dose response 11 when considering all application for women 12 particularly with patent tubes, correct? 13 MR. HEGARTY: Objection to the 14 form. 15 THE WITNESS: That is 16 correct. 17 BY MR. TISI: 18 Q. Would you go to page Table III, 19 please? 20 A. Uh-huh. 21 Q. It says when you censured patients. 22 At the very bottom it says "Application censured." | 2 A. We saw the highest adjusted odds 3 ratio being in those that had greater than 10,000 4 applications when limiting this exposure 5 assessment. 6 Q. Okay. Did you see a dose response 7 when you compared 3,000, 3,000 to 10,000, and 8 greater than 10,000? 9 A. The risks 10 MR. HEGARTY: Objection to the 11 form. 12 THE WITNESS: The risks went 13 from 1.54 to 1.72 to 1.8. 14 BY MR. TISI: 15 Q. Were they all statistically 16 significant? 17 A. The confidence intervals did not 18 included 1. 19 Q. Okay. 20 A. Not yes, included 1 in all of 21 them. 22 Q. Now, counsel was asking questions |
| 2 that Dr. Cramer was an expert or consultant in 3 talc litigation at the time you wrote this 4 article? 5 MR. HEGARTY: Objection to the 6 form. 7 THE WITNESS: No. 8 BY MR. TISI: 9 Q. Okay. Now, in this article, you 10 concluded that there was, in fact, a dose response 11 when considering all application for women 12 particularly with patent tubes, correct? 13 MR. HEGARTY: Objection to the 14 form. 15 THE WITNESS: That is 16 correct. 17 BY MR. TISI: 18 Q. Would you go to page Table III, 19 please? 20 A. Uh-huh. 21 Q. It says when you censured patients. | 2 A. We saw the highest adjusted odds 3 ratio being in those that had greater than 10,000 4 applications when limiting this exposure 5 assessment. 6 Q. Okay. Did you see a dose response 7 when you compared 3,000, 3,000 to 10,000, and 8 greater than 10,000? 9 A. The risks 10 MR. HEGARTY: Objection to the 11 form. 12 THE WITNESS: The risks went 13 from 1.54 to 1.72 to 1.8. 14 BY MR. TISI: 15 Q. Were they all statistically 16 significant? 17 A. The confidence intervals did not 18 included 1. 19 Q. Okay. 20 A. Not yes, included 1 in all of 21 them. |

| Page 458 | | Page 460 |
|---|--|---|
| - | 1 | MR. HEGARTY: Objection to |
| | | form. |
| | | BY MR. TISI: |
| · · · · · · · · · · · · · · · · · · · | | Q. That's what you explained in your |
| | | in your expert report? |
| • | | A. In the methodology section of that |
| - | _ | report, yes. |
| | | Q. And it's what was published in the |
| | | peer-reviewed peer-reviewed literature; is that |
| | | correct? |
| • • | | MR. HEGARTY: Objection to |
| • | | form. |
| • | | THE WITNESS: Published in |
| | | this paper in 1999. |
| | | BY MR. TISI: |
| - | | Q. By the way, counsel spent a lot of |
| | | time asking about the National Cancer Institute |
| ~ · | | and how important an agency that is. |
| | | Could you tell us who funded your |
| | | research in 1999? |
| | | A. The National Cancer Institute. |
| · · · · · · · · · · · · · · · · · · · | | Q. Thank you very much. |
| - | | Oh, and by the way, at the very end |
| • | | of the article, they talk about you provide a |
| • | | |
| | 1 | Page 461 summary? |
| · · · · · · · · · · · · · · · · · · · | | A. Yes. "In summary, we have |
| | | demonstrated." |
| | _ | Q. Okay. It says, and I'll read it |
| | | into the record: |
| | | "In summary, we have demonstrated a |
| | | consistent association between talc and ovarian |
| 5 | | cancer that appears unlikely to be explained by |
| | | recall and confounding." |
| | | Do you see that? |
| | 11 | A. Yes. |
| | 12 | Q. Okay. So you talked about |
| | | consistency, correct? |
| | 14 | MR. HEGARTY: Objection to the |
| consistency, biologic plausibility, and dose | 15 | form. |
| | 16 | THE WITNESS: Yes. |
| response and whether or not there was evidence of | | BY MR. TISI: |
| response and whether or not there was evidence of a bias, correct? | 17 | D I WIK. 1131. |
| | 17 18 | |
| a bias, correct? A. That's correct. | | Q. Okay. A. Yes. |
| a bias, correct? | 18 | Q. Okay. |
| a bias, correct? A. That's correct. MR. HEGARTY: Objection to | 18 19 | Q. Okay.A. Yes.Q. You talked about whether or not it's |
| a bias, correct? A. That's correct. MR. HEGARTY: Objection to form. BY MR. TISI: | 18 19 20 | Q. Okay. A. Yes. Q. You talked about whether or not it's explained by these other biases that counsel was |
| a bias, correct? A. That's correct. MR. HEGARTY: Objection to form. BY MR. TISI: | 18 19 20 21 | Q. Okay.A. Yes.Q. You talked about whether or not it's explained by these other biases that counsel was |
| | methodology? A. Yes. Q. Okay. Here in your article, you describe the causal methodology that you, in fact used in this case, correct? MR. HEGARTY: Objection to the form. THE WITNESS: In this 1999 paper, I followed the approach that I've used for all of the research in trying to interpret the findings in the context of potential biases. BY MR. TISI: Q. Let's look at page 353 of your article, please, under the "Discussion" section. A. Uh-huh. Q. It says: "In our discussion, we will examine whether this association satisfies traditional criteria for a causal association including consistency and strength of the association, potential biases, dose response and biologic credibility." Do you see that? Page 459 A. Yes, I do. Q. Are those the very same things when you published those those in your peer-reviewed paper that you applied when you you and Dr. Rothman got together and re-reviewed the evidence in 2023? MR. HEGARTY: Objection to form. THE WITNESS: That's correct. BY MR. TISI: Q. Okay. So you looked at primarily you didn't list each and every one of the Bradford-Hill factors, right? You talked about primarily strength, | methodology? A. Yes. Q. Okay. Here in your article, you describe the causal methodology that you, in fact, 4 used in this case, correct? MR. HEGARTY: Objection to the form. THE WITNESS: In this 1999 paper, I followed the approach that I've used for all of the research in trying to interpret the findings in the context of potential biases. BY MR. TISI: Q. Let's look at page 353 of your article, please, under the "Discussion" section. A. Uh-huh. Q. It says: "In our discussion, we will examine whether this association satisfies traditional criteria for a causal association including consistency and strength of the association, potential biases, dose response and biologic credibility." Do you see that? Page 459 A. Yes, I do. Q. Are those the very same things when you published those those in your peer-reviewed paper that you applied when you you and Dr. Rothman got together and re-reviewed the evidence in 2023? MR. HEGARTY: Objection to form. THE WITNESS: That's correct. BY MR. TISI: Q. Okay. So you looked at primarily you didn't list each and every one of the Bradford-Hill factors, right? You talked about primarily strength, 14 |

| Page 462 | Page 464 |
|---|---|
| 1 THE WITNESS: Yes. | 1 anybody about your opinions about the biologic |
| 2 BY MR. TISI: | 2 plausibility of talc, about the potential for talc |
| 3 Q. Okay. You talked about, it says: | 3 reaching the ovaries, about the potential for |
| 4 "The dose-response relationship is | 4 asbestos contamination, that women ought to be |
| 5 weak but improved by considering factors such as | 5 told about about the risk or told to avoid the |
| 6 closure of the female tract, ovulation and | 6 risk, you wrote that all in the 1990s. |
| 7 exposure prior to pregnancy, and we have outlined | 7 Correct? |
| 8 a plausible biologic rationale for this | 8 A. Yes. |
| 9 association." | 9 MR. HEGARTY: Objection to the |
| Do you see that? | 10 form. |
| 11 A. Yes, I do. | 11 BY MR. TISI: |
| 12 Q. That's exactly the same kinds of | 12 Q. That was before you were ever |
| 13 things you talked about in your litigation report, | 13 contacted by any lawyers in this litigation, true? |
| 14 correct? | MR. HEGARTY: Object. |
| MR. HEGARTY: Objection to the | 15 BY MR. TISI: |
| 16 form. | 16 Q. By decades? |
| 17 THE WITNESS: Yes. | 17 A. Correct. |
| 18 BY MR. TISI: | 18 Q. True? |
| 19 Q. Okay. It says: | MR. HEGARTY: Objection to |
| 20 "We estimate that avoidance of talc | 20 form. |
| 21 in genital hygiene might reduce the occurrence of | 21 THE WITNESS: Yes. |
| 22 a highly lethal form of cancer by at least 10%." | 22 BY MR. TISI: |
| 23 Correct? | 23 Q. All right. Let's move on. |
| 24 A. Yes. | 24 Counsel asked you some questions |
| Page 463 | Page 465 |
| 1 MR. HEGARTY: Objection to the | 1 about your letter to the editor. |
| 2 form. | 2 Okay. Now, this would have been |
| 3 BY MR. TISI: | 3 after you had done some consulting with for |
| 4 Q. Okay. And that's something that was | |
| _ | 4 not made as an expert but was a consultant for |
| 5 published in the peer-reviewed literature, | 5 talc litigants, correct? |
| 5 published in the peer-reviewed literature,6 correct? | 5 talc litigants, correct? 6 MR. HEGARTY: Objection to the |
| 5 published in the peer-reviewed literature, 6 correct? 7 MR. HEGARTY: Objection to the | 5 talc litigants, correct? 6 MR. HEGARTY: Objection to the 7 form. |
| 5 published in the peer-reviewed literature, 6 correct? 7 MR. HEGARTY: Objection to the 8 form. | 5 talc litigants, correct? 6 MR. HEGARTY: Objection to the 7 form. 8 THE WITNESS: That is |
| 5 published in the peer-reviewed literature, 6 correct? 7 MR. HEGARTY: Objection to the 8 form. 9 THE WITNESS: Yes. | 5 talc litigants, correct? 6 MR. HEGARTY: Objection to the 7 form. 8 THE WITNESS: That is 9 correct. |
| 5 published in the peer-reviewed literature, 6 correct? 7 MR. HEGARTY: Objection to the 8 form. 9 THE WITNESS: Yes. 10 BY MR. TISI: | 5 talc litigants, correct? 6 MR. HEGARTY: Objection to the 7 form. 8 THE WITNESS: That is 9 correct. 10 BY MR. TISI: |
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| | Page 466 | Page 4 |
|---|--|---|
| 1 | Q. Okay. Now, Dr. Rothman. We've | 1 is that there was no biologic plausibility or he |
| | talked about Dr. Rothman's report. | 2 had concerns about biologic plausibility. |
| 3 | Do you know if Dr. Rothman actually | 3 Do you remember that testimony? |
| 4 | did a report for the talc industry? | 4 A. Yes. |
| 5 | MR. HEGARTY: Objection to | 5 MR. HEGARTY: Objection to the |
| 6 | form. | 6 form. |
| 7 | THE WITNESS: At the time | 7 BY MR. TISI: |
| 8 | that I wrote this letter? | 8 Q. All right. Is there any evidence |
| 9 | BY MR. TISI: | 9 here that the that Dr. Rothman was told that |
| 10 | Q. Yes. | 10 there were tests performed by Johnson & Johnson i |
| 11 | A. I did not know that. | 11 the 1970s and 1980s which showed asbestos in talc |
| 12 | Q. Have you subsequently learned that? | 12 MR. HEGARTY: Objection to |
| 13 | A. Yes. | 13 form. |
| 14 | Q. Okay. The report that counsel asked | 14 THE WITNESS: I didn't see |
| | you about was done at the request of the Cosmetic | 15 any of that. |
| | Toiletry Products I forget the acronym of it | 16 MR. HEGARTY: Lacks |
| 17 | | 17 foundation. Misstates the facts. |
| 18 | MR. HEGARTY: Objection to | 18 BY MR. TISI: |
| 19 | form. Lacks foundation. Also misstates | 19 Q. Could you go to |
| 20 | the facts. Calls for speculation. | 20 A. I didn't see it in the report. |
| - | BY MR. TISI: | 21 Q. Could you go to Section B of your |
| 22 | Q. Have you learned that that was | 22 expert report, please? I mean, Footnote B of your |
| | that was performed at the request of the talc | 23 expert report? |
| | industry? | 24 A. Okay. Okay. Footnote A. Footnote |
| | Page 467 | , , , , , , , , , , , , , , , , , , , |
| 1 | A. Yes. | 1 B. Yes. |
| 2 | Q. Okay. | 2 Q. Okay. In Footnote B |
| 3 | A. That is that is my understanding | 2 A This is the William Lance? |
| | - · · · · · · · · · · · · · · · · · · · | 3 A. This is the William Longo? |
| 4 | of that report. | |
| 5 | of that report. Q. Now, you have been asked about that, | 4 Q. Right. |
| 5 | • | 4 Q. Right. 5 A. Okay. |
| 5 6 | Q. Now, you have been asked about that, | 4 Q. Right. 5 A. Okay. 6 Q. But there's also a reference to a |
| 5 6 7 | Q. Now, you have been asked about that, and I can certainly show you what Dr. Rothman | 4 Q. Right. 5 A. Okay. 6 Q. But there's also a reference to a s 7 Hopkins exhibit. |
| 5 6 7 8 | Q. Now, you have been asked about that, and I can certainly show you what Dr. Rothman said, but counsel selectively asked you questions | 4 Q. Right. 5 A. Okay. 6 Q. But there's also a reference to a s 7 Hopkins exhibit. |
| 5 6 7 8 | Q. Now, you have been asked about that, and I can certainly show you what Dr. Rothman said, but counsel selectively asked you questions about Dr. Rothman's report, but I'm going to ask you about it. | 4 Q. Right. 5 A. Okay. 6 Q. But there's also a reference to a s 7 Hopkins exhibit. 8 Do you see that? |
| 5 6 7 8 9 | Q. Now, you have been asked about that, and I can certainly show you what Dr. Rothman said, but counsel selectively asked you questions about Dr. Rothman's report, but I'm going to ask you about it. | 4 Q. Right. 5 A. Okay. 6 Q. But there's also a reference to a 7 Hopkins exhibit. 8 Do you see that? 9 A. Yes. |
| 5 6 7 8 9 10 11 | Q. Now, you have been asked about that, and I can certainly show you what Dr. Rothman said, but counsel selectively asked you questions about Dr. Rothman's report, but I'm going to ask you about it. A. Okay. | 4 Q. Right. 5 A. Okay. 6 Q. But there's also a reference to a 7 Hopkins exhibit. 8 Do you see that? 9 A. Yes. 10 Q. Okay. And do you recall counsel |
| 5 6 7 8 9 10 11 | Q. Now, you have been asked about that, and I can certainly show you what Dr. Rothman said, but counsel selectively asked you questions about Dr. Rothman's report, but I'm going to ask you about it. A. Okay. Q. First of all, here is Exhibit Number | 4 Q. Right. 5 A. Okay. 6 Q. But there's also a reference to a 7 Hopkins exhibit. 8 Do you see that? 9 A. Yes. 10 Q. Okay. And do you recall counsel 11 asked you questions about about references to |
| 5 6 7 8 9 10 11 12 | Q. Now, you have been asked about that, and I can certainly show you what Dr. Rothman said, but counsel selectively asked you questions about Dr. Rothman's report, but I'm going to ask you about it. A. Okay. Q. First of all, here is Exhibit Number P7, I believe. A. This goes to you. | 4 Q. Right. 5 A. Okay. 6 Q. But there's also a reference to a 8 7 Hopkins exhibit. 8 Do you see that? 9 A. Yes. 10 Q. Okay. And do you recall counsel 11 asked you questions about about references to 12 asbestos in talc, and you mentioned Dr. Longo, and |
| 5 6 7 8 9 10 11 12 13 | Q. Now, you have been asked about that, and I can certainly show you what Dr. Rothman said, but counsel selectively asked you questions about Dr. Rothman's report, but I'm going to ask you about it. A. Okay. Q. First of all, here is Exhibit Number P7, I believe. A. This goes to you. MR. TISI: Is it P7? | 4 Q. Right. 5 A. Okay. 6 Q. But there's also a reference to a 8 7 Hopkins exhibit. 8 Do you see that? 9 A. Yes. 10 Q. Okay. And do you recall counsel 11 asked you questions about about references to 12 asbestos in talc, and you mentioned Dr. Longo, and 13 he asked you all the questions about him being an |
| 5 6 7 8 9 10 11 12 13 14 | Q. Now, you have been asked about that, and I can certainly show you what Dr. Rothman said, but counsel selectively asked you questions about Dr. Rothman's report, but I'm going to ask you about it. A. Okay. Q. First of all, here is Exhibit Number P7, I believe. A. This goes to you. MR. TISI: Is it P7? MR. HEGARTY: That's what I | 4 Q. Right. 5 A. Okay. 6 Q. But there's also a reference to a 7 Hopkins exhibit. 8 Do you see that? 9 A. Yes. 10 Q. Okay. And do you recall counsel 11 asked you questions about about references to 12 asbestos in talc, and you mentioned Dr. Longo, and 13 he asked you all the questions about him being an 14 expert for plaintiffs and all that? All that? |
| 5 6 7 8 9 10 11 12 13 14 15 | Q. Now, you have been asked about that, and I can certainly show you what Dr. Rothman said, but counsel selectively asked you questions about Dr. Rothman's report, but I'm going to ask you about it. A. Okay. Q. First of all, here is Exhibit Number P7, I believe. A. This goes to you. MR. TISI: Is it P7? MR. HEGARTY: That's what I have. | 4 Q. Right. 5 A. Okay. 6 Q. But there's also a reference to a 7 Hopkins exhibit. 8 Do you see that? 9 A. Yes. 10 Q. Okay. And do you recall counsel 11 asked you questions about about references to 12 asbestos in talc, and you mentioned Dr. Longo, and 13 he asked you all the questions about him being an 14 expert for plaintiffs and all that? All that? 15 A. (Nods head). |
| 5 6 7 8 9 10 11 12 13 14 15 16 | Q. Now, you have been asked about that, and I can certainly show you what Dr. Rothman said, but counsel selectively asked you questions about Dr. Rothman's report, but I'm going to ask you about it. A. Okay. Q. First of all, here is Exhibit Number P7, I believe. A. This goes to you. MR. TISI: Is it P7? MR. HEGARTY: That's what I have. MR. TISI: P7. | 4 Q. Right. 5 A. Okay. 6 Q. But there's also a reference to a 7 Hopkins exhibit. 8 Do you see that? 9 A. Yes. 10 Q. Okay. And do you recall counsel 11 asked you questions about about references to 12 asbestos in talc, and you mentioned Dr. Longo, and 13 he asked you all the questions about him being an 14 expert for plaintiffs and all that? All that? 15 A. (Nods head). 16 Q. Okay. You remember the Hopkins |
| 5 6 7 8 9 10 11 12 13 14 15 16 17 | Q. Now, you have been asked about that, and I can certainly show you what Dr. Rothman said, but counsel selectively asked you questions about Dr. Rothman's report, but I'm going to ask you about it. A. Okay. Q. First of all, here is Exhibit Number P7, I believe. A. This goes to you. MR. TISI: Is it P7? MR. HEGARTY: That's what I have. MR. TISI: P7. (Document marked for | 4 Q. Right. 5 A. Okay. 6 Q. But there's also a reference to a 7 Hopkins exhibit. 8 Do you see that? 9 A. Yes. 10 Q. Okay. And do you recall counsel 11 asked you questions about about references to 12 asbestos in talc, and you mentioned Dr. Longo, and 13 he asked you all the questions about him being an 14 expert for plaintiffs and all that? All that? 15 A. (Nods head). 16 Q. Okay. You remember the Hopkins 17 exhibit was produced by J&J's witness, correct? |
| 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 | Q. Now, you have been asked about that, and I can certainly show you what Dr. Rothman said, but counsel selectively asked you questions about Dr. Rothman's report, but I'm going to ask you about it. A. Okay. Q. First of all, here is Exhibit Number P7, I believe. A. This goes to you. MR. TISI: Is it P7? MR. HEGARTY: That's what I have. MR. TISI: P7. (Document marked for | 4 Q. Right. 5 A. Okay. 6 Q. But there's also a reference to a 7 Hopkins exhibit. 8 Do you see that? 9 A. Yes. 10 Q. Okay. And do you recall counsel 11 asked you questions about about references to 12 asbestos in talc, and you mentioned Dr. Longo, and 13 he asked you all the questions about him being an 14 expert for plaintiffs and all that? All that? 15 A. (Nods head). 16 Q. Okay. You remember the Hopkins 17 exhibit was produced by J&J's witness, correct? 18 MR. HEGARTY: Objection to the |
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| 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 | Q. Now, you have been asked about that, and I can certainly show you what Dr. Rothman said, but counsel selectively asked you questions about Dr. Rothman's report, but I'm going to ask you about it. A. Okay. Q. First of all, here is Exhibit Number P7, I believe. A. This goes to you. MR. TISI: Is it P7? MR. HEGARTY: That's what I have. MR. TISI: P7. (Document marked for identification as Exhibit P7.) BY MR. TISI: Q. Here you go. | 4 Q. Right. 5 A. Okay. 6 Q. But there's also a reference to a 7 Hopkins exhibit. 8 Do you see that? 9 A. Yes. 10 Q. Okay. And do you recall counsel 11 asked you questions about about references to 12 asbestos in talc, and you mentioned Dr. Longo, and 13 he asked you all the questions about him being an 14 expert for plaintiffs and all that? All that? 15 A. (Nods head). 16 Q. Okay. You remember the Hopkins 17 exhibit was produced by J&J's witness, correct? 18 MR. HEGARTY: Objection to the 19 form. Lacks foundation. Calls for 20 speculation. 21 THE WITNESS: I don't know 22 who. I don't know who. I don't know |
| 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 | Q. Now, you have been asked about that, and I can certainly show you what Dr. Rothman said, but counsel selectively asked you questions about Dr. Rothman's report, but I'm going to ask you about it. A. Okay. Q. First of all, here is Exhibit Number P7, I believe. A. This goes to you. MR. TISI: Is it P7? MR. HEGARTY: That's what I have. MR. TISI: P7. (Document marked for identification as Exhibit P7.) BY MR. TISI: Q. Here you go. Now, first of all, is there any | 4 Q. Right. 5 A. Okay. 6 Q. But there's also a reference to a 7 Hopkins exhibit. 8 Do you see that? 9 A. Yes. 10 Q. Okay. And do you recall counsel 11 asked you questions about about references to 12 asbestos in talc, and you mentioned Dr. Longo, and 13 he asked you all the questions about him being an 14 expert for plaintiffs and all that? All that? 15 A. (Nods head). 16 Q. Okay. You remember the Hopkins 17 exhibit was produced by J&J's witness, correct? 18 MR. HEGARTY: Objection to the 19 form. Lacks foundation. Calls for 20 speculation. 21 THE WITNESS: I don't know 22 who. I don't know who. I don't know |

| | Page 470 | | Page 472 |
|--|--|--|--|
| 1 | Q. Okay. | 1 | dose response? |
| 2 | A who put that forward. | 2 | A. I do. |
| 3 | Q. Okay. I'm going to represent to you | 3 | Q. Okay. And that would have been |
| 4 | that there is evidence in this case that that | 4 | based on your study? |
| 5 | William Hopkins was one of the people at the at | 5 | MR. HEGARTY: Objection to the |
| 6 | the ISRTP meeting in 1995 and was a J&J employee | 6 | form. |
| 7 | testified to test results that showed asbestos in | 7 | THE WITNESS: Yes. |
| 8 | talc. I'll represent to you that. | 8 | BY MR. TISI: |
| 9 | Did you see any reference to that in | 9 | Q. Okay. Now, Dr. Rothman's report was |
| 10 | Dr. Rothman's report when he was asked to do | 10 | written in 2000, correct? |
| 11 | something, file this report by the talc industry? | 11 | A. That's correct. |
| 12 | A. I didn't. | 12 | Q. Okay. When he wrote his report with |
| 13 | MR. HEGARTY: Objection to the | 13 | you in 2023, in the 23 years that had passed |
| 14 | form. | 14 | between his report and the time that you that |
| 15 | THE WITNESS: I did not. | 15 | you issued your report, you and he both noted that |
| 16 | MR. HEGARTY: Counsel, did you | 16 | over time there was evidence of a dose response |
| 17 | say that Dr. Hopkins prepared Exhibit | 17 | when considered against the backdrop of exposure, |
| 18 | Number 28? | 18 | true? |
| 19 | MR. TISI: Oh, yeah, he did. | 19 | MR. HEGARTY: Objection to the |
| 20 | I sure did. | 20 | form. |
| 21 | MR. HEGARTY: I would disagree | 21 | THE WITNESS: We reported |
| 22 | with that. | 22 | that. |
| 23 | MR. TISI: Okay. | 23 | BY MR. TISI: |
| 24 | MR. HEGARTY: It was a | 24 | Q. Right. |
| | Page 471 | | Page 473 |
| 1 | plaintiffs' lawyer prepared document. | 1 | And that's not unusual in science |
| 2 | MR. TISI: With with | 2 | where evidence accumulates over time and becomes |
| 3 | Dr. Hopkins giving testimony at the time. | 3 | more or less persuasive, ,correct? |
| 4 | MR. HEGARTY: But you're | 4 | MR. HEGARTY: Objection to the |
| 5 | telling you were telling Dr. Harlow | 5 | form. |
| 6 | MR. TISI: At the deposition. | 6 | THE WITNESS: Yes. |
| 7 | MR. HEGARTY: that | 7 | BY MR. TISI: |
| 8 | Dr. Hopkins prepared Exhibit 28. | 8 | Q. Okay. All right. Going back to the |
| 9 | MR. TISI: Okay. Fine. We | 9 | letter to the editor that you wrote. |
| 10 | can disagree about the characterization. | 10 | You were asked some questions about |
| 10 | can alsagree about the characterization. | l . | |
| 10 11 | E | 11 | and even some, I would call, insulting questions |
| | He prepared it at a deposition | | |
| 11 | He prepared it at a deposition under oath with with with the | | and even some, I would call, insulting questions |
| 11 12 | He prepared it at a deposition under oath with with the attorney asking him questions about the | 12 | and even some, I would call, insulting questions about the statistically unsophisticated conclusion |
| 11 12 13 | He prepared it at a deposition under oath with with the attorney asking him questions about the test results. | 12 13 | and even some, I would call, insulting questions about the statistically unsophisticated conclusion that that was reached about patent tubes. |
| 11 12 13 14 | He prepared it at a deposition under oath with with with the attorney asking him questions about the test results. But let's go let's go | 12 13 14 | and even some, I would call, insulting questions about the statistically unsophisticated conclusion that that was reached about patent tubes. Do you remember that? |
| 11 12 13 14 15 16 | He prepared it at a deposition under oath with with with the attorney asking him questions about the test results. But let's go let's go | 12 13 14 15 | and even some, I would call, insulting questions about the statistically unsophisticated conclusion that that was reached about patent tubes. Do you remember that? MR. HEGARTY: Objection to the |
| 11 12 13 14 15 16 | He prepared it at a deposition under oath with with with the attorney asking him questions about the test results. But let's go let's go through let's go through this. BY MR. TISI: | 12 13 14 15 16 17 | and even some, I would call, insulting questions about the statistically unsophisticated conclusion that that was reached about patent tubes. Do you remember that? MR. HEGARTY: Objection to the form. |
| 11 12 13 14 15 16 17 | He prepared it at a deposition under oath with with with the attorney asking him questions about the test results. But let's go let's go through let's go through this. BY MR. TISI: Q. It talks about a dose response. | 12 13 14 15 16 17 | and even some, I would call, insulting questions about the statistically unsophisticated conclusion that that was reached about patent tubes. Do you remember that? MR. HEGARTY: Objection to the form. THE WITNESS: Yes. |
| 11 12 13 14 15 16 17 18 19 | He prepared it at a deposition under oath with with with the attorney asking him questions about the test results. But let's go let's go through let's go through this. BY MR. TISI: Q. It talks about a dose response. | 12 13 14 15 16 17 18 | and even some, I would call, insulting questions about the statistically unsophisticated conclusion that that was reached about patent tubes. Do you remember that? MR. HEGARTY: Objection to the form. THE WITNESS: Yes. BY MR. TISI: |
| 11 12 13 14 15 16 17 18 19 | He prepared it at a deposition under oath with with with the attorney asking him questions about the test results. But let's go let's go through let's go through this. BY MR. TISI: Q. It talks about a dose response. A. Are we going back to Dr. Rothman's report? | 12 13 14 15 16 17 18 19 20 | and even some, I would call, insulting questions about the statistically unsophisticated conclusion that that was reached about patent tubes. Do you remember that? MR. HEGARTY: Objection to the form. THE WITNESS: Yes. BY MR. TISI: Q. Okay. First of all, you've |
| 11 12 13 14 15 16 17 18 19 20 | He prepared it at a deposition under oath with with with the attorney asking him questions about the test results. But let's go let's go through let's go through this. BY MR. TISI: Q. It talks about a dose response. A. Are we going back to Dr. Rothman's report? Q. Correct. | 12 13 14 15 16 17 18 19 20 | and even some, I would call, insulting questions about the statistically unsophisticated conclusion that that was reached about patent tubes. Do you remember that? MR. HEGARTY: Objection to the form. THE WITNESS: Yes. BY MR. TISI: Q. Okay. First of all, you've you've written a lot in the epidemiology |
| 11 12 13 14 15 16 17 18 19 20 21 | He prepared it at a deposition under oath with with with the attorney asking him questions about the test results. But let's go let's go through let's go through this. BY MR. TISI: Q. It talks about a dose response. A. Are we going back to Dr. Rothman's report? Q. Correct. A. Okay. | 12 13 14 15 16 17 18 19 20 21 22 | and even some, I would call, insulting questions about the statistically unsophisticated conclusion that that was reached about patent tubes. Do you remember that? MR. HEGARTY: Objection to the form. THE WITNESS: Yes. BY MR. TISI: Q. Okay. First of all, you've you've written a lot in the epidemiology literature. |

| | Page 474 | | Page 476 |
|----------------------------|--|----------------|--|
| 1 | MR. HEGARTY: Objection to the | 1 | And although we don't know |
| 2 | form. | 2 | whether or not the association in |
| - | SY MR. TISI: | 3 | case-control study are true, in many |
| 4 | Q. Have you ever seen their name come | 4 | times case-control studies can |
| | p in any of the talc literature that you | 5 | overestimate the association, but it |
| | eviewed? | 6 | certainly seems like they are, as we |
| 7 | A. No. | 7 | indicated, quite comparable. |
| 8 | Q. Okay. I'm going to refer you to | 8 | And I believe that's what |
| _ | what Dr putting aside what you and Dr. Rothman | 9 | she's suggesting here. |
| 1 | vrote, I want to ask you about what Dr how | l . | BY MR. TISI: |
| | Or. O'Brien characterized her own study. Okay? | 11 | Q. Okay. And particularly with women |
| 12 | Look at Exhibit Number did we | | with patent tubes, correct? |
| | nark this? | 13 | MR. HEGARTY: Objection to the |
| 14 | A. Are we talking about the letter to | 14 | form. |
| | ne editor? | 15 | THE WITNESS: Well, in the |
| 16 | MR. HEGARTY: We did mark it. | 16 | next in the next paragraph, |
| _ | BY MR. TISI: | 17 | Dr. O'Brien specifically says: |
| 18 | Q. Actually, I'll just you have it | 18 | "We completely agree with |
| | front of you, don't you? | 19 | Dr. Harlow and colleagues that our |
| 20 | A. I do. | 20 | results, particularly the analyses |
| 21 | MR. TISI: I'll give you my | 21 | limited to women with intact reproductive |
| 22 | | 22 | tracts, should not be discounted because |
| 23 | copy. MR. HEGARTY: Okay. | 23 | of lack of statistical significance." |
| 24 | MR. TISI: I'll give you my | l | BY MR. TISI: |
| 24 | | 24 | |
| 1 | Page 475 copy. You can look at it. We have it | 1 | Q. Okay. Let me show you something |
| 2 | previously marked. | l . | else that Dr. O'Brien said subsequent to the |
| | BY MR. TISI: | 3 | publication of the article. |
| 4 | Q. Do you see where Dr if I could | 4 | I'm going to show you an article I'm |
| 1 | come around the table and look at you. | 5 | going to have marked as Exhibit Number wha |
| 6 | Do you see where Dr. O'Brien writes: | 1 | exhibit number are we at now? |
| 7 | "If cohort studies pooled HR 1.8 are | 7 | MR. HEGARTY: P8. |
| | ikely biased towards the null in case-control | 8 | MR. TISI: P8. |
| | tudies are likely biased away from the null the | 9 | MR. HEGARTY: That's what I |
| | rue association may be somewhere in the middle. | 10 | have. |
| 11 | Do you see that? | 11 | (Document marked for |
| 12 | A. I do. | 12 | identification as Exhibit P8.) |
| 13 | Q. Does Dr how do you interpret | l | BY MR. TISI: |
| | what Dr. O'Brien says about the relevancy of her | 14 | Q. This is an article from 2023, |
| 1 | • | l | December. So this would have been after your |
| 1 | tudy in either proving or disproving an association between talc and ovarian cancer? | | expert report, correct? |
| | | l | • |
| 17 | MR. HEGARTY: Objection to the | 17 | A. Yes, because I did not see this at |
| | form. | 18 | the time I was doing the review. On You saw that in connection with your |
| 18 | THE WITNESS. Chala and a | 」19 | Q. You saw that in connection with your |
| 18 19 | THE WITNESS: She's saying | 20 | proporation for this deposition to deve some at ? |
| 18 19 20 | exactly what we have indicated in that | | preparation for this deposition today, correct? |
| 18 19 20 21 | exactly what we have indicated in that the because of the limitations on the | 21 | A. That's correct. |
| 18 19 20 21 22 | exactly what we have indicated in that the because of the limitations on the exposure assessment in the cohort | 21 22 | A. That's correct.Q. And one of the things she says |
| 18 19 20 21 | exactly what we have indicated in that the because of the limitations on the | 21 22 23 | A. That's correct. |

| | Page 478 | | Page 480 |
|----|--|-------|---|
| 1 | or adulthood with uterine fibroids diagnoses." | 1 | BY MR. TISI: |
| 2 | | 2 | Q. I meant to say EPA. Environmental |
| 3 | - | 3 | Protection Agency. |
| 4 | Q. Okay. And she talks about she | 4 | A. I'm sorry. I thought I heard EPA. |
| 5 | • | 5 | Q. Now, when you were asked questions, |
| 6 | - | 6 | do you know of any governmental agency that ever |
| 7 | and animal models have shown that once deposited | 7 | concluded that talc-containing asbestos can cause |
| 8 | onto epithelial cells, it can cause chronic | 8 | ovarian cancer? |
| 9 | inflammation, leading to a series of mutagenic | 9 | Do you remember those questions? |
| 10 | events, and this effect is worse in talc | 10 | A. Yes. |
| 11 | contaminated with asbestos, a known carcinogen." | 11 | MR. HEGARTY: Objection to the |
| 12 | Correct? | 12 | form. |
| 13 | MR. HEGARTY: Objection to | 13 | BY MR. TISI: |
| 14 | form. | 14 | Q. Okay. And are you aware that the |
| 15 | THE WITNESS: That is | 15 | United States Environmental Protection Agency |
| 16 | correct. And what's interesting is she's | 16 | included just that very same thing? |
| 17 | E | 17 | MR. HEGARTY: I'm going to |
| 18 | article from 2019. | 18 | object to the form. They did not say |
| 1 | BY MR. TISI: | 19 | that talc use causes ovarian cancer. |
| 20 | Q. Okay. | 20 | BY MR. TISI: |
| 21 | A. So this isn't new information. | 21 | Q. Talc-containing asbestos causes |
| 22 | Q. All right. My point is: When you | | ovarian cancer? |
| | talk about to the extent that counsel is | 23 | MR. HEGARTY: Well, I didn't |
| 24 | vouching for Dr. O'Brien's conclusions, one of the | 24 | are you representing that's that what |
| | Page 479 | | Page 481 |
| | things she talks about is the exact same biologic | 1 | that document says? |
| 1 | plausible mechanism you and Dr. Rothman talked | 2 | MR. TISI: I'm going to |
| 3 | 1 1 | 3 | show I'm going to show him what it |
| 4 | 3 | 4 | says. |
| 5 | | 5 | MR. HEGARTY: All right. |
| 6 | | 6 | THE WITNESS: I know that |
| | BY MR. TISI: | 7 | |
| 8 | , , | 8 | publications or recent documents that say |
| | biologic plausibility you talked about in the | 9 | that asbestos causes ovarian cancer was |
| 1 | 1990s and published in the peer-reviewed medical | 10 | recent. |
| | literature, true? | | BY MR. TISI: |
| 12 | | 12 | Q. And they also say that talc can |
| 13 | 3 | l | contain asbestos asbestos, correct? |
| 14 | | 14 | MR. HEGARTY: Objection to the |
| | BY MR. TISI: | 15 | |
| 16 | | 16 | THE WITNESS: I if you |
| | about things that are subsequent to your expert | 17 | show it to me, I will agree. |
| 1 | report. | l | BY MR. TISI: On In fact in Section B. I will show |
| 19 | • | 19 | Q. In fact, in Section B I will show |
| 1 | come out with a with a final rule with respect | 20 21 | you this in a minute. A. Yeah. |
| | to with respect to asbestos and, among other | 21 22 | |
| 23 | things, ovarian cancer? A. Yes. | l | Q. In Footnote B of your expert report, you refer to FDA testing of Johnson & Johnson's |
| 23 | | | talc, correct? |
| | MR. HEOAKI I. Did you say I'DA! | | |

| | Page 482 | Page 484 |
|----|---|---|
| 1 | A. That's correct. | 1 Q. Going to the next page. Page |
| 2 | Q. And what did they find? | 2 it's paginated at the top. I think it's the |
| 3 | A. They found contamination. | 3 third fourth page in. 21973. |
| 4 | MR. HEGARTY: Objection to the | 4 A. Yes. |
| 5 | form. | 5 Q. Middle paragraph, middle column. |
| | BY MR. TISI: | 6 A. Yes. |
| 7 | Q. Okay. | 7 Q. Paragraph it says at the bottom |
| 8 | A. They found contamination. | 8 it says: |
| 9 | MR. TISI: Let me mark as | 9 "Additionally, some" |
| 10 | Exhibit Number 9. | 10 A. Hold on. Let me find where it is. |
| 11 | THE COURT REPORTER: 9. | 11 MR. HEGARTY: I'm not |
| 12 | MR. TISI: Thank you for | |
| 13 | keeping track for me. I'm trying to move | following where you are either. THE WITNESS: Okay. |
| 14 | | 14 MR. TISI: (Indicates). |
| | quickly. | 15 MR. HEGARTY: What's the |
| 15 | THE WITNESS: This is 7. Oh, | |
| 16 | no. Wait a minute. | heading on the section? |
| 17 | MR. TISI: That's 8. This | MR. TISI: "Background." |
| 18 | is 9. | 18 MR. HEGARTY: Okay. And |
| 19 | THE WITNESS: Okay. | you're talking about? |
| 20 | (Document marked for | 20 MR. TISI: The middle, |
| 21 | identification as Exhibit P9.) | 21 three-fourths down. |
| 22 | MR. TISI: For the record, | MR. HEGARTY: Okay. Where the |
| 23 | this is Federal Register dated March 28, | word starts "Additionally"? |
| 24 | 2024. | 24 MR. TISI: "Additionally." |
| | Page 483 | |
| 1 | MR. HEGARTY: Do you have a | 1 THE WITNESS: Hold on. I'm |
| 2 | copy for me? | 2 looking for that. Can I see that again? |
| 3 | Can I have that clip that's in | 3 BY MR. TISI: |
| 4 | front of you? It's right there. | 4 Q. Sure. |
| 5 | MR. TISI: Yes. | 5 A. I want to make sure that I'm |
| 6 | MR. HEGARTY: Thank you. | 6 following this. |
| 7 | BY MR. TISI: | 7 I got it. Okay. Uh-huh. |
| 8 | Q. First of all, do you see on the | 8 Q. It says: |
| 9 | left-hand side it says | 9 "Additionally, some talc deposits |
| 10 | A. Under "Summary"? | 10 and articles containing talc have been shown to |
| 11 | Q. Under "Summary," it says is issuing | 11 contain asbestos. Thus, EPA recognizes that |
| 12 | for | 12 certain uses of talc may present the potential for |
| 13 | "The Environmental Protection Agency | 13 asbestos exposure." |
| 14 | (EPA or the Agency) is issuing this final rule | Do you see that? |
| 1 | under the Toxic Substances Control Act to address | 15 A. I do. |
| 1 | to the extent necessary the unreasonable risk of | 16 Q. Okay. And in fact, you were aware |
| 1 | injury to health presented by chrysotile asbestos | 17 that the FDA did test Johnson & Johnson's talc and |
| | based on the risks posed by certain conditions of | 18 did find talc in it, true? |
| | use. The injuries to human health include." | 19 A. Yes. |
| 20 | Could you tell us what they say? | 20 MR. HEGARTY: Objection to the |
| 21 | A. "The injuries to human health | 21 form. |
| 1 | include mesothelioma and lung, ovarian, and | 22 BY MR. TISI: |
| | laryngeal cancers resulting from chronic | 23 Q. And one more question before I ask |
| | inhalation exposure to chrysotile asbestos." | 24 you the conclusion here. |
| 4+ | initiation exposure to enrysome aspestos. | 27 you the conclusion note. |

| 1 | Page 486 | | Page 488 |
|--|---|----------------------|--|
| 1 | It says | 1 | you were asked some questions about inhalation |
| 2 | MR. HEGARTY: Where are you | | that this that this supports your opinion that |
| 3 | reading? | | that is an alternative plausible biologic |
| _ | BY MR. TISI: | | mechanism for for the possibility of talc |
| 5 | Q. On page 21975 under the title | 5 | causing ovarian cancer? |
| 6 | "Description of Unreasonable Risk." | 6 | MR. HEGARTY: Objection to |
| 7 | A. Uh-huh. | 7 | form. |
| 8 | Q. Do you see that? | 8 | THE WITNESS: From |
| 9 | A. Yes. | 9 | inhalation, yes. |
| 10 | Q. Okay. It says and it talks about | | BY MR. TISI: |
| 11 | | 11 | Q. Okay. And so whether or not |
| | says: | | asbestos is the cause of talc of talc causing |
| 13 | "Since there was no | | ovarian cancer, it is a plausible is it a |
| | exposure-response data for ovarian and laryngeal | | plausible mechanism? |
| | | 15 | A. Yes. |
| | a direct estimate of risk from ovarian and | 16 | MR. HEGARTY: Objection to the |
| | laryngeal cancer could not be made for the | 17 | form. |
| | inhalation unit risk calculation." | | BY MR. TISI: |
| 19 | A. Uh-huh. | 19 | Q. Okay. Is there evidence in the |
| 20 | Q. It says: | | scientific and medical literature, including by |
| 21 | "An adjustment factor for ovarian | 21 | |
| | | 22 | A. Yes. |
| | value estimates to correct for the underestimated | 23 | MR. HEGARTY: Objection to the |
| | total cancer risk derived from only lung cancer | 24 | form. |
| | Page 487 | | Page 489 |
| 1 | and mesothelioma," it says. | 1 | BY MR. TISI: |
| 2 | And then it goes on to say: | 2 | Q. In fact, that was also reported |
| 3 | "Total cancer risk encompassing all | 3 | |
| 4 | four cancers known to be caused by exposure to | 4 | A. Yes. |
| 5 | chrysotile asbestos." | 5 | MR. HEGARTY: Objection to the |
| 6 | • | 6 | form. |
| 7 | A. I do. | 7 | BY MR. TISI: |
| 8 | Q. And if you go above, it says | 8 | Q. So when counsel says, does any |
| 9 | right under the description, it says: | 9 | federal does any governmental body ever say |
| 10 | "Unreasonable risk includes the risk | | that talc can cause ovarian cancer, we have two |
| | of mesothelioma and lung, ovarian, and laryngea | | |
| | cancers from chronic inhalation exposure." | | Environmental Protection Agency, saying talc with |
| 13 | A. Yes. | 13 | asbestos can cause ovarian cancer. |
| 14 | Q. Okay. Let me ask you a couple | 14 | Is that true or not true? |
| | questions about that. | 15 | MR. HEGARTY: Misstates the |
| 13 | • | 16 | document. |
| 15 16 | | 1 | THE WITNESS: It is what they |
| 16 | | 17 | THE WITHESS. It is what they |
| 16 | opinion that talc-containing asbestos is a | 17 18 | say. |
| 16 17 18 | opinion that tale-containing asbestos is a | 18 | |
| 16 17 18 | opinion that talc-containing asbestos is a biologically plausible mechanism for causing ovarian cancer? | 18 | say. BY MR. TISI: |
| 16 17 18 19 | opinion that talc-containing asbestos is a biologically plausible mechanism for causing ovarian cancer? A. Yes. | 18 19 20 | say. BY MR. TISI: Q. Okay. And, in fact, if you go one |
| 16 17 18 19 20 | opinion that talc-containing asbestos is a biologically plausible mechanism for causing ovarian cancer? | 18 19 20 21 | say. BY MR. TISI: Q. Okay. And, in fact, if you go one step further, Health Canada says they're not even |
| 16 17 18 19 20 21 22 | opinion that talc-containing asbestos is a biologically plausible mechanism for causing ovarian cancer? A. Yes. MR. HEGARTY: Objection to the | 18 19 20 21 | say. BY MR. TISI: Q. Okay. And, in fact, if you go one step further, Health Canada says they're not even |

| | Page 490 | | Page 492 |
|--|---|--|--|
| 1 | ovarian cancer, correct? | 1 | MR. HEGARTY: And I need to do |
| 2 | MR. HEGARTY: Objection to the | 2 | so before the flight leaves. |
| 3 | form. | 3 | MR. TISI: I'm just going to |
| 4 | THE WITNESS: Yes. | 4 | , , |
| 5 | | 5 | I need a break. Just one area that I |
| - | | 6 | know I have to I know I have to talk |
| 6 | Q. Now, did they unlike the FDA in | 7 | about here. Probably about Michelle, |
| | the 2014 letter that you were shown before by the FDA | 8 | do you I have about five minutes, 10 |
| - | | 9 | minutes. |
| 9 | | 10 | |
| 10 | Q did Health Canada actually show its work? | 11 | MS. PARFITT: 7:02. What time |
| 12 | | 12 | |
| 13 | MR. HEGARTY: Objection to the form. | 13 | is your flight? MR. HEGARTY: 8:15. So I'm |
| 14 | THE WITNESS: Yes. | 13 | |
| | | 15 | |
| 16 | BY MR. TISI: Q. Did it list all the studies it | 16 | |
| | Q. Did it list all the studies it considered? | 17 | |
| | | 18 | it, Mark. MR. HEGARTY: No, I know. I'm |
| 18 | A. Yes, it did. | 19 | • |
| 19 | Q. Did it go through the Bradford-Hill the Bradford considerations and | 20 | |
| | | | 3 & |
| | talked about dose response and talk about biologic | 21 22 | MS. PARFITT: Yeah, why don't we take a quick break. |
| | plausibility and all of those things, correct? | 23 | _ |
| 23 24 | A. Yes. | 23 | MR. TISI: Oh, yeah. We can do that. |
| 24 | MR. HEGARTY: Objection to the | 24 | uo mat. |
| | D 401 | | D 402 |
| 1 | Page 491 | 1 | Page 493 MR HEGARTY: I have to call |
| 1 2 | form. | 1 2 | MR. HEGARTY: I have to call |
| 2 | form. BY MR. TISI: | 2 | MR. HEGARTY: I have to call and reschedule before it takes off. |
| 2 3 | form. BY MR. TISI: Q. Do you know from reading that | 2 3 | MR. HEGARTY: I have to call and reschedule before it takes off. (Recess: 7:02 p.m |
| 2 3 4 | form. BY MR. TISI: Q. Do you know from reading that document we can take it out, but I'm trying to | 2 3 4 | MR. HEGARTY: I have to call and reschedule before it takes off. (Recess: 7:02 p.m 7:34 p.m.) |
| 2 3 4 5 | form. BY MR. TISI: Q. Do you know from reading that document we can take it out, but I'm trying to be respectful of the time here. | 2 3 4 5 | MR. HEGARTY: I have to call and reschedule before it takes off. (Recess: 7:02 p.m 7:34 p.m.) BY MR. TISI: |
| 2 3 4 | form. BY MR. TISI: Q. Do you know from reading that document we can take it out, but I'm trying to be respectful of the time here. Do you know you said it was | 2 3 4 5 6 | MR. HEGARTY: I have to call and reschedule before it takes off. (Recess: 7:02 p.m 7:34 p.m.) BY MR. TISI: Q. I'm going to try to do this in a |
| 2 3 4 5 6 7 | form. BY MR. TISI: Q. Do you know from reading that document we can take it out, but I'm trying to be respectful of the time here. Do you know you said it was peer-reviewed. | 2 3 4 5 6 7 | MR. HEGARTY: I have to call and reschedule before it takes off. (Recess: 7:02 p.m 7:34 p.m.) BY MR. TISI: Q. I'm going to try to do this in a really summary way because it's late. |
| 2 3 4 5 6 7 8 | form. BY MR. TISI: Q. Do you know from reading that document we can take it out, but I'm trying to be respectful of the time here. Do you know you said it was peer-reviewed. Do you know whether or not J&J | 2 3 4 5 6 7 8 | MR. HEGARTY: I have to call and reschedule before it takes off. (Recess: 7:02 p.m 7:34 p.m.) BY MR. TISI: Q. I'm going to try to do this in a really summary way because it's late. A. (Nods head). |
| 2 3 4 5 6 7 8 9 | form. BY MR. TISI: Q. Do you know from reading that document we can take it out, but I'm trying to be respectful of the time here. Do you know you said it was peer-reviewed. Do you know whether or not J&J actually have you been informed that J&J | 2 3 4 5 6 7 8 9 | MR. HEGARTY: I have to call and reschedule before it takes off. (Recess: 7:02 p.m 7:34 p.m.) BY MR. TISI: Q. I'm going to try to do this in a really summary way because it's late. A. (Nods head). Q. If you would go you remember the |
| 2 3 4 5 6 7 8 9 10 | form. BY MR. TISI: Q. Do you know from reading that document we can take it out, but I'm trying to be respectful of the time here. Do you know you said it was peer-reviewed. Do you know whether or not J&J actually have you been informed that J&J actually met with Health Canada and actually | 2 3 4 5 6 7 8 9 | MR. HEGARTY: I have to call and reschedule before it takes off. (Recess: 7:02 p.m 7:34 p.m.) BY MR. TISI: Q. I'm going to try to do this in a really summary way because it's late. A. (Nods head). Q. If you would go you remember the discussion of the PDQ? |
| 2 3 4 5 6 7 8 9 10 | form. BY MR. TISI: Q. Do you know from reading that document we can take it out, but I'm trying to be respectful of the time here. Do you know you said it was peer-reviewed. Do you know whether or not J&J actually have you been informed that J&J actually met with Health Canada and actually provided not only plaintiffs' expert reports in | 2 3 4 5 6 7 8 9 10 11 | MR. HEGARTY: I have to call and reschedule before it takes off. (Recess: 7:02 p.m 7:34 p.m.) BY MR. TISI: Q. I'm going to try to do this in a really summary way because it's late. A. (Nods head). Q. If you would go you remember the discussion of the PDQ? A. Yes. |
| 2 3 4 5 6 7 8 9 10 11 12 | form. BY MR. TISI: Q. Do you know from reading that document we can take it out, but I'm trying to be respectful of the time here. Do you know you said it was peer-reviewed. Do you know whether or not J&J actually have you been informed that J&J actually met with Health Canada and actually provided not only plaintiffs' expert reports in litigation, but also defendants' expert reports in | 2 3 4 5 6 7 8 9 10 11 12 | MR. HEGARTY: I have to call and reschedule before it takes off. (Recess: 7:02 p.m 7:34 p.m.) BY MR. TISI: Q. I'm going to try to do this in a really summary way because it's late. A. (Nods head). Q. If you would go you remember the discussion of the PDQ? A. Yes. Q. Okay. And you remember the |
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| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 | form. BY MR. TISI: Q. Do you know from reading that document we can take it out, but I'm trying to be respectful of the time here. Do you know you said it was peer-reviewed. Do you know whether or not J&J actually have you been informed that J&J actually met with Health Canada and actually provided not only plaintiffs' expert reports in litigation, but also defendants' expert reports in litigation? A. I did not know that. MR. HEGARTY: Objection to the form. BY MR. TISI: Q. Okay. Now, let's talk a bit about dose response. MR. HEGARTY: Let me interrupt | 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 | MR. HEGARTY: I have to call and reschedule before it takes off. (Recess: 7:02 p.m 7:34 p.m.) BY MR. TISI: Q. I'm going to try to do this in a really summary way because it's late. A. (Nods head). Q. If you would go you remember the discussion of the PDQ? A. Yes. Q. Okay. And you remember the discussion about the question about whether or not there was inconsistency between O'Brien and the Woolen article. Do you remember that? A. Yes. Q. Okay. I'm happy to show you both of them. A. I have them in front of me. |
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| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 | form. BY MR. TISI: Q. Do you know from reading that document we can take it out, but I'm trying to be respectful of the time here. Do you know you said it was peer-reviewed. Do you know whether or not J&J actually have you been informed that J&J actually met with Health Canada and actually provided not only plaintiffs' expert reports in litigation, but also defendants' expert reports in litigation? A. I did not know that. MR. HEGARTY: Objection to the form. BY MR. TISI: Q. Okay. Now, let's talk a bit about dose response. MR. HEGARTY: Let me interrupt for just a second. How much longer are you going to go? I have to call to | 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 | MR. HEGARTY: I have to call and reschedule before it takes off. (Recess: 7:02 p.m 7:34 p.m.) BY MR. TISI: Q. I'm going to try to do this in a really summary way because it's late. A. (Nods head). Q. If you would go you remember the discussion of the PDQ? A. Yes. Q. Okay. And you remember the discussion about the question about whether or not there was inconsistency between O'Brien and the Woolen article. Do you remember that? A. Yes. Q. Okay. I'm happy to show you both of them. A. I have them in front of me. Q. Okay. But based upon your review of O'Brien, what did Woolen add what did Woolen |
| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 | form. BY MR. TISI: Q. Do you know from reading that document we can take it out, but I'm trying to be respectful of the time here. Do you know you said it was peer-reviewed. Do you know whether or not J&J actually have you been informed that J&J actually met with Health Canada and actually provided not only plaintiffs' expert reports in litigation, but also defendants' expert reports in litigation? A. I did not know that. MR. HEGARTY: Objection to the form. BY MR. TISI: Q. Okay. Now, let's talk a bit about dose response. MR. HEGARTY: Let me interrupt for just a second. How much longer are you going to go? I have to call to change my flight. | 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 | MR. HEGARTY: I have to call and reschedule before it takes off. (Recess: 7:02 p.m 7:34 p.m.) BY MR. TISI: Q. I'm going to try to do this in a really summary way because it's late. A. (Nods head). Q. If you would go you remember the discussion of the PDQ? A. Yes. Q. Okay. And you remember the discussion about the question about whether or not there was inconsistency between O'Brien and the Woolen article. Do you remember that? A. Yes. Q. Okay. I'm happy to show you both of them. A. I have them in front of me. Q. Okay. But based upon your review of |

| Page 494 | Page 496 |
|--|--|
| 1 trying to assess exposure in a more comprehensive | 1 using the O'Brien data. |
| 2 way. | 2 BY MR. TISI: |
| 3 Q. Okay. | 3 Q. Okay. In what patient population? |
| 4 A. I believe that's what they were | 4 A. The Nurses' Health Study. |
| 5 doing. | 5 Q. Okay. Was that the highest |
| 6 Q. Okay. And we're talking about | 6 exposure? |
| 7 exposure, we're talking about to be clear, | 7 A. I believe it was. |
| 8 we're talking about numbers of applications, which | 8 Q. Okay. Okay. Did Woolen support |
| 9 is the thing that you have been concerned about | 9 does Woolen support your opinion that with |
| 10 since the 1990s, correct? | 10 increasing increasing exposure comes increasing |
| 11 A. That's correct. | 11 risk? |
| 12 Q. Okay. And to be simple about it, | 12 A. It certainly confirms or supports |
| 13 it's number of years times number of applications, | 13 it, yes. |
| 14 correct? | 14 Q. Okay. Let me see. I do not think |
| 15 MR. HEGARTY: Objection to the | 15 that I have any other things, but let me just |
| 16 form. | 16 let me just take a quick look here. |
| 17 THE WITNESS: Taking into | 17 Can you pull out the Taher article |
| 18 account both years and applications is | 18 that's Exhibit Number 26 since we're talking about |
| the appropriate way to do it. | 19 dose response. |
| 20 BY MR. TISI: | 20 A. Yeah, because the one I have in my |
| 21 Q. Okay. Did she do that? Did | 21 in my notebook is the wrong one. So do we have |
| 22 Woolen did the Woolen paper actually do that? | 22 that? |
| 23 A. Well, I can't see exactly where they | |
| 24 did that. | Q. Yeah, I have a copy of it.A. Okay. |
| | |
| Page 495 1 Q. Okay. So let me ask you this | Page 497 MR. TISI: Do you mind showing |
| 2 question. | 2 him my copy? Actually, I think I have |
| 3 A. Yeah. | 3 it. |
| 4 Q. There was the suggestion before, and | 4 THE WITNESS: Because I |
| 5 I want to be clear. | 5 reviewed I reviewed the correct one, |
| 6 Is Woolen inconsistent with or did | 6 but copied the wrong one. |
| 7 it just look at different things than O'Brien? | 7 (Discussion off the record) |
| 8 A. Yeah. No. | 8 THE WITNESS: Yeah, that's the |
| 9 MR. HEGARTY: Objection to | 9 one. |
| 10 form. | 10 BY MR. TISI: |
| 11 THE WITNESS: No, I do not see | 11 Q. I'm going to ask you to look at |
| them as being substantially different. | 12 something different than on Michelle's copy, but |
| 13 BY MR. TISI: | 13 this is Exhibit Number 23. |
| 14 Q. Okay. | 14 A. Okay. |
| 15 A. Particularly when you look at the | 15 Q. I'll get you a clean one if you need |
| 16 confidence intervals. | 16 to but here is |
| 17 Q. What did Woolen look at and what did | |
| 18 Woolen find? | 18 Q. I'm going to ask you to look at |
| 19 A. Woolen found | 19 table number this is Exhibit Number 23, but I'm |
| 20 MR. HEGARTY: Objection to the | 20 going to show you a clean copy of it. |
| 21 form. | 21 If you would go to Table 3. |
| 22 THE WITNESS: Woolen found | 22 A. Oh, you have it. Okay. |
| | |
| 123 overall association of 1.4 with a | |
| overall association of 1.4 with a confidence interval of 1.17 and 1.68 | Q. Do you seeA. Right. |

| 3:1 | .6-md-02738-MAS-RLS Document 332 PageID: 26 | | |
|-----|--|----|--|
| | Page 498 | | Page 500 |
| 1 | Q there is a table? | 1 | at. |
| 2 | A. You mean the figure? (Indicates). | 2 | MR. TISI: Okay. |
| 3 | Q. No, I mean the next page. Can I see | 3 | FURTHER EXAMINATION |
| | it? I just want to make sure. | 4 | |
| 5 | A. (Indicates). | 5 | Q. Do you have the exhibits in front of |
| 6 | Q. No, that's not the right one. I | - | you, Dr. Harlow, that Mr. Tisi asked you about? |
| | don't have my copy. | 7 | A. I have them. Yes, I guess they're |
| 8 | Here it is. Table 2. | | right here. Okay. |
| 9 | A. Table 2. Uh-huh. Yes. | 9 | Q. The first study he asked you about |
| 10 | Q. Okay. Do you see them break out, as | | was P1, "The association between douching, genital |
| | you did, break out frequency of exposure? | | talc use, and the risk of prevalent and incident |
| 12 | A. They have frequency of use, duration | | cervical cancer"? |
| | of use. | 13 | A. Yes. |
| 14 | Q. Okay. When they look at frequency | 14 | Q. You don't cite to this article in |
| | greater than 10,000, do you see evidence of a dose | | this body of your report, correct? |
| | response? | 16 | A. No, I do not. |
| 17 | A. No. No. The frequency is low, | 17 | Q. Did you find this article on your |
| | medium, high and duration is 10 years, 10 to 20 | | own? |
| | years, 20 plus years. | 19 | A. No. |
| 20 | Q. Okay. Do you see when you look at | 20 | Q. Did plaintiffs' counsel provide it |
| | those together, you see increasing increasing | | to you? |
| | dose response? | 22 | A. They did. |
| 23 | A. I don't | 23 | Q. Did you even reference this article |
| 24 | MR. HEGARTY: Objection to the | | in your list of references or Materials Considered |
| 24 | | 24 | · · |
| . | Page 499 | | Page 501 |
| 1 | form. | | list, if you know? |
| 2 | THE WITNESS: I don't see | 2 | A. Yeah. No, I did not. |
| 3 | them put together. | 3 | MR. TISI: Well, it's in the |
| | BY MR. TISI: | 4 | Materials Considered list we provided |
| 5 | Q. Let me see. I'm not looking at the | 5 | you. |
| | right one. Table 2, 3.2. | 6 | MR. HEGARTY: And that's |
| 7 | MS. PARFITT: Table 2, Chris. | 7 | for is it in the box? |
| | BY MR. TISI: | 8 | MR. TISI: It's in the box. |
| 9 | Q. Actually, let me just let me | 9 | It's in the box. |
| | just I don't have my copy. So I'm not going to | 10 | MR. HEGARTY: Okay. |
| | do that. | 11 | MR. TISI: May I have it? |
| 12 | I have no other questions right now. | | BY MR. HEGARTY: |
| | Why don't we go through and let Mr. Hegarty ask | 13 | Q. Please turn over to page 2 of this |
| | his questions. | | article. |
| 15 | (Recess: 7:41 p.m | 15 | A. Yes. Under what section? |
| 16 | 7:47 p.m.) | 16 | MR. TISI: Here. |
| 17 | MR. HEGARTY: At the outset, I | 17 | THE WITNESS: Okay. |
| 18 | just want to state an objection for the | | BY MR. HEGARTY: |
| 19 | record, that is, to the extent | 19 | Q. In the second I'm sorry. In the |
| 20 | Dr. Rothman I'm sorry Dr. Harlow | | first full paragraph, second sentence, it reads: |
| 21 | was asked about or brought up opinions | 21 | "Observational studies have |
| 22 | concerning studies or facts that were not | | documented associations between douching and HPV |
| 23 | previously disclosed in his expert | | cervical lesions or progression of cervical |
| 24 | report, and that's where I'll leave it | 24 | lesions from low to high grade. Additional, |

| | Page 502 | | Page 504 |
|----|--|----|--|
| 1 | several retrospective case-control studies have | 1 | and ovarian cancer? |
| | reported positive association between douching and | 2 | A. Well, for one thing, The Sister |
| | cervical cancer. We did not identify any | | Study excluded 160 cases, and so I don't have a |
| | prospective studies of relationship between | | lot of confidence in their findings with respect |
| | douching and cervical cancer. Such studies are | | to tale and ovarian cancer. |
| | needed to rule out recall bias which can result | 6 | Q. But did I properly summarize the |
| | when an individual affected by a disease | | results of that Sister Study as published in the |
| | over-report their exposure to an agent of | | Gonzalez paper? |
| | concern." | 9 | A. Yes, there was there was an |
| 10 | | | associate between powder talc use and subsequent |
| | You agree with that statement, don't | 1 | ovarian cancer website. Douching was more common |
| 12 | you? | | |
| | MR. TISI: Objection. | | among talc users, yes. |
| 13 | THE WITNESS: (Reviews | 13 | Oh, well. Douching was more common |
| 14 | document.) | | among talc users and douching at baseline was |
| 15 | Well, again, you if it's | | associated with increased subsequent risk of |
| 16 | conducted appropriately and you can | | ovarian cancer. Yes, that's what they said. |
| 17 | actually identify those who were exposed | 17 | Q. With regard to the exposure data |
| 18 | to douching and those who were not from | 1 | that the Gonzalez study collected, it asked about |
| 19 | the beginning of their exposure | | talc use in the prior 12 months, correct? |
| 20 | assessment, yes, then it would eliminate | 20 | A. That's correct. |
| 21 | recall bias. | 21 | Q. If talc use is an habitual practice, |
| | BY MR. HEGARTY: | | then talc use in the last 12 months would actually |
| 23 | Q. What O'Brien and her coauthors are | | reflect long-term talc use, correct? |
| 24 | saying here is that they looked at the | 24 | A. Possibly, but, again, the problem is |
| | Page 503 | | Page 505 |
| 1 | case-control studies, but that prospective studies | | is that these are women who are who were |
| 2 | | | followed forward in time who for whatever reason |
| 3 | That's what that says, right? | | had not developed ovarian cancer by the time they |
| 4 | A. That's what they're alluding to. | | were enrolled in this by the time they were |
| 5 | Q. Okay. Thank you. | | followed in this study. So what we call a |
| 6 | Have you analyzed or let me start | | depletion of susceptibles, for whatever reason |
| 7 | over. | | they could very well have been resilient to the |
| 8 | 1 | 8 | development of ovarian cancer. |
| 9 | • | 9 | So I can't with that kind of |
| | a risk factor/cause for ovarian cancer? | 10 | severe selection bias, I can't I can't really |
| 11 | A. I have not I have not done a | | put any stock in this in these findings, |
| | primary analysis around that, but I would have to | 12 | particularly with respect to talc and ovarian |
| | look in my previous studies to see whether I | 13 | cancer. |
| | looked at douching as a potential covariate. | 14 | |
| 15 | Q. Do you consider douching as a risk | 15 | regard to identifying exposure of talc in the last |
| 16 | factor for ovarian cancer? | 16 | 12 months. |
| 17 | A. I have not done an extensive search | 17 | A. If some |
| | of the literature as to what it suggests there, | 18 | Q. If it is a habitual habit, wouldn't |
| | but I believe I was looking at douching as a | 19 | that indicate longer term use than simply in the |
| 20 | potential covariate. | 20 | last 12 months? |
| 21 | Q. Do you recall that the Gonzalez | 21 | A. Well, if it's just asking, have you |
| 22 | study concerning The Sister Study did find an | 22 | ever used it in the last 12 months, no, that would |
| 23 | association statistically significant between | 23 | not. But if you had used it in the last 12 months |
| 24 | douching and ovarian cancer but not for talc use | 24 | every day applying it to the perineum, yes, to me, |

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1 that would suggest that they were probably using

- 2 it for longer periods of time.
- But if they had simply asked, have 3
- 4 you used talc in the last 12 months, it's your
- 5 opinion that that would not tell you anything
- 6 about long-term use before the last 12 months?
- I wouldn't -- I would be hesitant to
- 8 make that assumption.
- 9 Please turn to Plaintiff's
- 10 Exhibit 2, your study with Dr. Weiss.
- 11 A. Yes.
- 12 That's entitled "A Case-Control O.
- 13 Study of Borderline Ovarian Tumors: The Influence
- 14 of Perineal Exposure to Talc."
- 15 A. Yes.
- 16 Q. Do you have that in front of you?
- 17 A. Yes, I do.
- 18 Q. In this study, you reported/found as
- 19 stated in the abstract that neither the perineal
- 20 application of baby powder nor the perineal
- 21 application of corn starch was associated with an
- 22 appreciable altered risk of borderline ovarian
- 23 tumors, correct?

1

24 That's what we found. Α

Q. Did you report in this study that

- 2 was marked as Exhibit P2 that women reported using
- 3 Shower to Shower?
- 4 A. I don't -- I'm trying to look to see
- 5 if we specifically stated that that was -- it was
- 6 asked.

12

- 7 (Reviews document.)
- 8 No, I did not report that.
- 9 Well, let me just quickly look in
- 10 the methods of the assessment of -- of it.
- (Reviews document.) 11
 - "Baby powder, deodorizing powder,
- 13 and other unspecified talcum or dusting powders or
- 14 as corn starch."
- 15 So I cannot specifically say that
- 16 the deodorizing powder was talc-based, but if it
- 17 was corn starch, they would have said corn starch,
- 18 which we specifically asked that.
- 19 In fact, if you look over in the
- 20 "Methods" section on page 2 ---
- 21 A. Yes.
- 22 -- your open-ended question asked
- 23 women to specify the type but not the brand name,
- 24 correct?

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- Q. So you did not find an association
- 2 between talcum powder use and borderline tumors in
- 3 this study, correct?
- 4 Actually, that's not true. We found
- 5 an association with deodorizing powders and
- 6 ovarian cancer, and deodorizing powders are known 7 to be talc-based.
- The question, though, put to the
- 9 women in the study was not whether your
- 10 deodorizing powder contained talc, it was simply,
- 11 did you use deodorizing powder, correct?
- 12 A. That's correct.
- 13 Q. In the end, you don't know whether
- 14 the deodorizing powder that the women reported
- 15 using contained talc, right?
- 16 Well, many of them suggested or even
- 17 indicated that it was Shower to Shower, and I know
- 18 that Shower to Shower deodorizing powder does
- 19 contain talc. I don't know of deodorizing powders
- 20 other than corn starch, and we specifically asked
- 21 about corn starch, would other than -- other than
- 22 those that are specifically indicated as corn
- 23 starch, deodorizing powder I would make the
- 24 assumption was a talc-based product.

- 1 A. That is correct.
- 2 Q. So they would not in answering that
- 3 question have specified Shower to Shower, which is
- 4 a brand name product, correct?
- 5 We did not analyze that data. We
- 6 did collect that information, but it was not
- 7 considered reliable to be able to actually look at
- 8 it that way, and so that's the reason why we
- 9 analyzed it this way.
- 10 Q. In this study, you did not find that
- 11 perineal application of baby powder was associated
- 12 with an appreciable altered risk of borderline
- 13 ovarian tumors, correct?
- 14 That's correct. Except that
- 15 deodorizing powder in combination was associated
- 16 with risk. As you can see in Table 1, deodorizing
- 17 powder only was associated with 3.5 fold
- 18 association and deodorizing powder only or in
- 19 combination was associated with 2.8 fold
- 20 association.
- 21 Q. My question, though, was as specific
- 22 to baby powder.
- 23 A. That is correct. Baby powder.
 - Q. You did not find an association

24

| | Page 510 | | Page 512 |
|--|--|--|--|
| 1 | between baby powder use and borderline ovarian | 1 | Q. Next you say: |
| 2 | tumors, correct? | 2 | "Because our associations are based |
| 3 | A. It yes. | 3 | upon responses from participating cases and |
| 4 | Q. I believe you testified earlier, but | 4 | controls, the validity of our results depends upon |
| 5 | please correct me if I'm wrong, that you did not | 5 | the assumption that respondents and |
| 6 | do a separate analysis let me restart that. | 6 | non-respondents were similar with respect to talc |
| 7 | Strike that. | 7 | and other relevant exposures, or that the |
| 8 | Am I correct that you do not have an | 8 | magnitude of any respondent-non-respondent |
| 9 | opinion as to whether talcum powder use causes | 9 | difference was similar for cases and controls. |
| 10 | borderline tumors? | 10 | Because the interview provided the only source of |
| 11 | A. I cannot make that assumption only | 11 | 'exposure' information, we were unable to assess |
| 12 | because I believe this may be the only study that | 12 | the likelihood of this assumption." |
| 13 | specifically focused on borderline ovarian tumors. | 13 | That's all accurate, correct? |
| 14 | Q. Do you have an opinion as to whether | 14 | A. That is correct. Because non |
| 15 | talcum powder use can cause endometrial cancer, | 15 | because nondifferential misclassification would |
| 16 | that is, cancer of the endometrium? | 16 | drive the association towards the null, which |
| 17 | A. I have not reviewed that literature. | 17 | means that the associations we see are an |
| 18 | Q. Please turn to Exhibit Number 3. | 18 | underestimate of the true association. |
| 19 | That is P3. I'm sorry. | 19 | Q. You were also asked questions about |
| 20 | A. Right. Is that the 1992 article? | 20 | the ISRTP let me start over. |
| 21 | Q. Yes, Doctor. With regard to that | 21 | You were also asked questions about |
| 22 | 1 0 | 22 | the FDA workshop that you attended back in 1994, |
| 23 | This first, the last full paragraph | | correct? |
| 24 | on the right-hand side, it reads: | 24 | A. Yes. |
| | | | |
| | Page 511 | | Page 513 |
| 1 | "Non-causal explanations are | 1 | Q. Who invited you to that workshop? |
| 2 | "Non-causal explanations are possible in any epidemiologic research." | 2 | Q. Who invited you to that workshop?A. I don't recall who actually sent me |
| 3 | "Non-causal explanations are possible in any epidemiologic research." Is that a correct statement? | 2 3 | Q. Who invited you to that workshop?A. I don't recall who actually sent methe invitation. I was invited by whoever was |
| 2 3 4 | "Non-causal explanations are possible in any epidemiologic research." Is that a correct statement? A. Yes. | 2 3 4 | Q. Who invited you to that workshop? A. I don't recall who actually sent me the invitation. I was invited by whoever was coordinating it. |
| 2 3 4 5 | "Non-causal explanations are possible in any epidemiologic research." Is that a correct statement? A. Yes. Q. Okay. You go on to write: | 2 3 4 5 | Q. Who invited you to that workshop? A. I don't recall who actually sent me the invitation. I was invited by whoever was coordinating it. MR. TISI: I'm sorry. That's |
| 2 3 4 5 6 | "Non-causal explanations are possible in any epidemiologic research." Is that a correct statement? A. Yes. Q. Okay. You go on to write: "We cannot rule out the possibility | 2 3 4 5 6 | Q. Who invited you to that workshop? A. I don't recall who actually sent me the invitation. I was invited by whoever was coordinating it. MR. TISI: I'm sorry. That's my sticky note on it, which is not |
| 2 3 4 5 6 7 | "Non-causal explanations are possible in any epidemiologic research." Is that a correct statement? A. Yes. Q. Okay. You go on to write: "We cannot rule out the possibility of differential over- or under-reporting of talc | 2 3 4 5 6 7 | Q. Who invited you to that workshop? A. I don't recall who actually sent me the invitation. I was invited by whoever was coordinating it. MR. TISI: I'm sorry. That's my sticky note on it, which is not intended. |
| 2 3 4 5 6 7 8 | "Non-causal explanations are possible in any epidemiologic research." Is that a correct statement? A. Yes. Q. Okay. You go on to write: "We cannot rule out the possibility of differential over- or under-reporting of talc exposure in our cases and controls, especially in | 2 3 4 5 6 7 8 | Q. Who invited you to that workshop? A. I don't recall who actually sent me the invitation. I was invited by whoever was coordinating it. MR. TISI: I'm sorry. That's my sticky note on it, which is not intended. THE WITNESS: Sorry. |
| 2 3 4 5 6 7 8 9 | "Non-causal explanations are possible in any epidemiologic research." Is that a correct statement? A. Yes. Q. Okay. You go on to write: "We cannot rule out the possibility of differential over- or under-reporting of talc exposure in our cases and controls, especially in those with reproductive events that enhance odds | 2 3 4 5 6 7 8 9 | Q. Who invited you to that workshop? A. I don't recall who actually sent me the invitation. I was invited by whoever was coordinating it. MR. TISI: I'm sorry. That's my sticky note on it, which is not intended. THE WITNESS: Sorry. BY MR. HEGARTY: |
| 2 3 4 5 6 7 8 9 10 | "Non-causal explanations are possible in any epidemiologic research." Is that a correct statement? A. Yes. Q. Okay. You go on to write: "We cannot rule out the possibility of differential over- or under-reporting of talc exposure in our cases and controls, especially in those with reproductive events that enhance odds ratios." | 2 3 4 5 6 7 8 9 10 | Q. Who invited you to that workshop? A. I don't recall who actually sent me the invitation. I was invited by whoever was coordinating it. MR. TISI: I'm sorry. That's my sticky note on it, which is not intended. THE WITNESS: Sorry. BY MR. HEGARTY: Q. Please look at P4, the Carr 1995 |
| 2 3 4 5 6 7 8 9 10 | "Non-causal explanations are possible in any epidemiologic research." Is that a correct statement? A. Yes. Q. Okay. You go on to write: "We cannot rule out the possibility of differential over- or under-reporting of talc exposure in our cases and controls, especially in those with reproductive events that enhance odds ratios." Is that a correct statement? | 2 3 4 5 6 7 8 9 10 11 | Q. Who invited you to that workshop? A. I don't recall who actually sent me the invitation. I was invited by whoever was coordinating it. MR. TISI: I'm sorry. That's my sticky note on it, which is not intended. THE WITNESS: Sorry. BY MR. HEGARTY: Q. Please look at P4, the Carr 1995 paper that you talked about with |
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| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 | "Non-causal explanations are possible in any epidemiologic research." Is that a correct statement? A. Yes. Q. Okay. You go on to write: "We cannot rule out the possibility of differential over- or under-reporting of talc exposure in our cases and controls, especially in those with reproductive events that enhance odds ratios." Is that a correct statement? A. That's what I said. That's correct, yes. Q. You go on to say: "In addition, though we were successful in interviewing 69% of eligible ovarian cancer cases and 81% of eligible controls contacted, we cannot assess whether the cases and controls not interviewed could have selectively differentiated could have selectively differed in their reproductive characteristics or in their use of talc-containing body powders." | 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 | Q. Who invited you to that workshop? A. I don't recall who actually sent me the invitation. I was invited by whoever was coordinating it. MR. TISI: I'm sorry. That's my sticky note on it, which is not intended. THE WITNESS: Sorry. BY MR. HEGARTY: Q. Please look at P4, the Carr 1995 paper that you talked about with A. Yes. Q counsel for plaintiffs and you talked about with me. A. Yes. Q. You told counsel for plaintiffs that you felt that the summary as reported by Mr. Carr was not fair and balanced. Is that what you believe? A. I do believe that to be the case with respect to the epidemiologic evidence. Q. Have you ever said or made that |
| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 | "Non-causal explanations are possible in any epidemiologic research." Is that a correct statement? A. Yes. Q. Okay. You go on to write: "We cannot rule out the possibility of differential over- or under-reporting of talc exposure in our cases and controls, especially in those with reproductive events that enhance odds ratios." Is that a correct statement? A. That's what I said. That's correct, yes. Q. You go on to say: "In addition, though we were successful in interviewing 69% of eligible ovarian cancer cases and 81% of eligible controls contacted, we cannot assess whether the cases and controls not interviewed could have selectively differentiated could have selectively differed in their reproductive characteristics or in their use of talc-containing body powders." That's a correct statement as well? | 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 | Q. Who invited you to that workshop? A. I don't recall who actually sent me the invitation. I was invited by whoever was coordinating it. MR. TISI: I'm sorry. That's my sticky note on it, which is not intended. THE WITNESS: Sorry. BY MR. HEGARTY: Q. Please look at P4, the Carr 1995 paper that you talked about with A. Yes. Q counsel for plaintiffs and you talked about with me. A. Yes. Q. You told counsel for plaintiffs that you felt that the summary as reported by Mr. Carr was not fair and balanced. Is that what you believe? A. I do believe that to be the case with respect to the epidemiologic evidence. |

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|---|--|
| 1 A. I have not. | 1 Q. Top left. |
| 2 Q. Have you ever made that statement to | 2 A. Oh. "Because the risk"? |
| 3 anyone outside of today's proceedings? | 3 Q. First full paragraph. |
| 4 A. I have not. | 4 A. Yep. Uh-huh. |
| 5 Q. And as we talked, you never did a | 5 Q. "Because the risk of any one outcome |
| 6 follow-up letter to the editor or other report | 6 is dependent upon both the frequency and length of |
| 7 where you commented on the summary that Carr | 7 the exposure, Harlow et al. (1992) created a |
| 8 provided in P4? | 8 continuous measure of total lifetime applications |
| 9 MR. TISI: Objection. | 9 for each case and control." |
| 10 BY MR. HEGARTY: | Do you remember talking to that with |
| 11 Q. Is that correct? | 11 plaintiffs' counsel? |
| MR. TISI: Objection. | 12 A. Yes. |
| 13 Misstates | 13 Q. And then I believe you testified |
| 14 THE WITNESS: I'd like | 14 that what that meant was that reporting only on |
| MR. TISI: Misstates what | 15 frequency or only on duration is a limitation when |
| happened, but go ahead. | 16 assessing essentially dose response. |
| 17 THE WITNESS: Am I allowed to | 17 Is that a fair summary? |
| 18 answer? | 18 A. I believe it is. |
| 19 MR. TISI: Yeah. | 19 Q. Do you have the Woolen paper in |
| THE WITNESS: The review that | 20 front of you? It's Exhibit 19. |
| I did in the same issue was my response | 21 A. I do. |
| 22 to that particular summary. | Q. Or your copy of the Woolen paper? |
| 23 BY MR. HEGARTY: | 23 A. Yeah. Yeah. Yeah, I do. |
| Q. And that review, which is P5? | Woolen is right here. Got it. |
| Page 515 | Page 51 |
| 1 A. Correct. | 1 Q. Thank you. |
| 2 Q. So you can look at P5. | The Woolen paper reported only on |
| 3 A. Yeah. | 3 frequency of use and risk of ovarian cancer, |
| 4 Q. I should say: In that review, you | 4 correct? |
| 5 did not make the statement that any summary of the | 5 A. Frequent use where they defined it |
| 6 proceedings was not fair and balanced, correct? | 6 as greater than 2 times per week. |
| 7 A. I would not have done that in a | 7 Q. So the only thing they reported with |
| 8 peer-reviewed article. | 8 regard to duration or frequency was as to more |
| 9 Q. You made the statement in response | 9 than 2 times a week, correct? |
| 10 to plaintiffs' counsel | 10 A. Yes, that's correct. |
| 11 A. Are we still on this article or have | 11 Q. They did not report a combined |
| 12 you moved off? | 12 cumulative exposure of dose of duration and |
| 13 Q. Let me see. I'm looking at my | 13 frequency, correct? |
| 14 okay. Yeah. I'm sorry. Please stay with P5. | 14 A. No. |
| Please turn over to 256, and this | 15 MR. TISI: Objection. |
| | 16 Misstates. |
| 16 was a statement you talked about with counsel for | |
| 16 was a statement you talked about with counsel for 17 plaintiff. | 17 BY MR. HEGARTY: |
| 16 was a statement you talked about with counsel for17 plaintiff.18 A. Uh-huh. | 17 BY MR. HEGARTY:18 Q. That would then be, according to |
| 16 was a statement you talked about with counsel for 17 plaintiff. 18 A. Uh-huh. 19 Q. The statement: "Because the risk of | 17 BY MR. HEGARTY: 18 Q. That would then be, according to 19 your testimony just a moment ago, a limitation |
| 16 was a statement you talked about with counsel for 17 plaintiff. 18 A. Uh-huh. 19 Q. The statement: "Because the risk of 20 any" | 17 BY MR. HEGARTY: 18 Q. That would then be, according to 19 your testimony just a moment ago, a limitation 20 what conclusions you can draw from the Woole |
| 16 was a statement you talked about with counsel for 17 plaintiff. 18 A. Uh-huh. 19 Q. The statement: "Because the risk of 20 any" 21 A. Well, just remind me where exactly | 17 BY MR. HEGARTY: 18 Q. That would then be, according to 19 your testimony just a moment ago, a limitation 20 what conclusions you can draw from the Woole 21 paper, correct? |
| 16 was a statement you talked about with counsel for 17 plaintiff. 18 A. Uh-huh. 19 Q. The statement: "Because the risk of 20 any" 21 A. Well, just remind me where exactly 22 it is, please. | 17 BY MR. HEGARTY: 18 Q. That would then be, according to 19 your testimony just a moment ago, a limitation 20 what conclusions you can draw from the Woole 21 paper, correct? 22 MR. TISI: Objection. |
| 16 was a statement you talked about with counsel for 17 plaintiff. 18 A. Uh-huh. 19 Q. The statement: "Because the risk of 20 any" 21 A. Well, just remind me where exactly | 17 BY MR. HEGARTY: 18 Q. That would then be, according to 19 your testimony just a moment ago, a limitation 20 what conclusions you can draw from the Woole 21 paper, correct? |

| | Page 518 | | Page 520 |
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| 1 | | 1 | agree. |
| 2 | · | 2 | Q. Okay. |
| 3 | * | 3 | A. It should be disclosed. |
| 4 | · · · · · · · · · · · · · · · · · · · | 4 | Q. And with regard to the Woolen |
| 5 | that most studies had not been able to do | 5 | A. Wait. Except that I do want to just |
| 6 | and that's to really look at one at | 6 | make make sure that you that it's clarified |
| 7 | the papers that provided the best | | that the first author, Sean Woolen, has no |
| 8 | information on more frequent use, and | 8 | relevant disclosures and Lazar, the second author, |
| 9 | that's why they included only those | 9 | has no relevant disclosures. And usually the |
| 10 | studies. | 10 | first author is the one that writes the paper and |
| 11 | That information available to | 11 | makes the ultimate decision on what is published. |
| 12 | them on greater than 2 times per week so | 12 | Q. Well, are you aware that the Woolen |
| 13 | that they could look at rather than | 13 | paper was started by Dr. Smith-Bindman as part of |
| 14 | just looking at any or none, they're now | 14 | an expert witness report that she prepared in the |
| 15 | able to look at greater than 2 times per | 15 | Pennsylvania state court case called Kliner versus |
| 16 | week versus none, and they see an | 16 | Johnson & Johnson? |
| 17 | association that's a bit stronger. | 17 | MR. TISI: Objection. |
| 18 | BY MR. HEGARTY: | 18 | THE WITNESS: I'm not aware |
| 19 | Q. Woolen does not talk about duration | 19 | of that. |
| 20 | of talc use, correct? | 20 | BY MR. HEGARTY: |
| 21 | A. Only to the extent that that's the | 21 | Q. Would that be something important |
| 1 | way they chose to do this analysis by selecting | 22 | for you to know? |
| 23 | those studies that had at least greater than 2 | 23 | MR. TISI: Objection. |
| 24 | times per week of exposure. | 24 | Misstates. |
| | Page 519 | | Page 521 |
| 1 | Q. Have you ever in any epidemiologic | 1 | THE WITNESS: Only if this |
| 2 | study of yours reported as to dose response only | 2 | information had not been peer-reviewed in |
| 3 | duration or only frequency? | 3 | the scientific literature. |
| 4 | | 4 | BY MR. HEGARTY: |
| 1 | individually, but also in combination when the | 5 | Q. Please turn over to Table 2 in the |
| 6 | data is available to me. | 6 | Woolen paper. |
| 7 | Q. Are you aware that with regard to | 7 | A. Yes. Table 2. Uh-huh. |
| 1 | the Woolen paper that one of the authors, | 8 | Q. With regard to the data that this |
| 1 | Dr. Smith-Bindman, is a plaintiffs' expert in this | 9 | Woolen paper combined, it included frequency data |
| 1 | same litigation that you are? | 10 | that was not consistent across all the studies, |
| 11 | | 11 | correct? |
| 12 | | 12 | A. That's correct. Well, yes, that's |
| | this paper over on page 2532? | | correct. |
| 14 | | 14 | Q. Then if you look down at the very |
| 15 | 11 1 | | bottom in Footnote 5, do you see with regard to |
| | you're an expert witness in talc litigation for | | the data from the O'Brien study that Dr that |
| 17 | * | | the Woolen paper only included data on women with |
| 18 | ŭ | | intact fallopian tubes? |
| 19 | | 19 | A. (Reviews document.) |
| 20 | | 20 | I do see that. Uh-huh. "To |
| 21 | that. | | harmonize with other publications." |
| | BY MR. HEGARTY: | 22 | Q. Have you looked at whether the other |
| 23 | | | publications only reported data on women with |
| 24 | A. In fact, I think they should. I | 24 | intact fallopian tubes? |

| | Page 522 | Page 5 |
|--|---|---|
| 1 | A. I have not. | 1 ratios were above 1. |
| 2 | Q. It | 2 Q. The only trend you found was what |
| 3 | A. You mean across all these other | 3 you reported at the end of that table; is that |
| 4 | studies? | 4 correct? |
| 5 | Q. That's right. | 5 A. Yes, that is that is the trend |
| 6 | A. Yeah. | 6 that is that is a trend that we reported when |
| 7 | Q. So to truly harmonize across all 11 | 7 we felt we adequately refined the exposure aligned |
| ' | studies, all 11 studies would need to report their | 8 with the biological plausibility that we were |
| | data only as to women with intact fallopian tubes, | 9 testing. |
| 1 | correct? | 10 Q. Please turn to the very last page |
| 11 | MR. TISI: Objection. | 11 that you were asked about by counsel for |
| 12 | THE WITNESS: Well, I would | 12 plaintiffs, particularly the very last sentence of |
| 13 | have to look at these articles. So | |
| | | 13 this study. 14 A. Of this article? |
| 14 | certainly I know that Cramer and Harlow | |
| 15 | would have that ability to provide to | 15 Q. Yes, sir. |
| 16 | to separate out that exposure. | 16 A. Okay. |
| 17 | I would have to look back at | 17 Q. The sentence about "Appropriate |
| 18 | the articles to see if all of these | 18 warnings should be provided." |
| 19 | articles specifically allowed for that | Do you see that sentence? |
| 20 | separation. | 20 A. Yes. |
| | BY MR. HEGARTY: | 21 "Appropriate warnings should be |
| 22 | Q. If they don't all allow for that | 22 provided to women about the potential risks of |
| | separation, then there would not be harmonization | 23 regular use of talc in the genital area." |
| 24 | across all the studies, correct? | Q. As we looked at today and as you are |
| | Page 523 | |
| 1 | A. I I think that it would not be | 1 aware, FDA disagrees with that statement, correct |
| 2 | the same across all studies. That's right. | MD TICL Objection |
| 1 2 | | 2 MR. TISI: Objection. |
| 3 | Q. You can put that document aside. | 3 Objection. Misstates the document. |
| 4 | Q. You can put that document aside.A. Okay. | |
| 4 5 | Q. You can put that document aside.A. Okay.Q. And please look at P6. | 3 Objection. Misstates the document. |
| 4 5 6 | Q. You can put that document aside.A. Okay.Q. And please look at P6.MR. TISI: How much time do we | 3 Objection. Misstates the document. 4 Misstates the document completely. 5 BY MR. HEGARTY: 6 Q. You can answer. |
| 4 5 6 7 | Q. You can put that document aside. A. Okay. Q. And please look at P6. MR. TISI: How much time do we have? I mean, in light of the fact I did | 3 Objection. Misstates the document. 4 Misstates the document completely. 5 BY MR. HEGARTY: 6 Q. You can answer. 7 A. Are you referring to the response to |
| 4 5 6 7 8 | Q. You can put that document aside. A. Okay. Q. And please look at P6. MR. TISI: How much time do we have? I mean, in light of the fact I did do longer, I'm giving you some leeway. | 3 Objection. Misstates the document. 4 Misstates the document completely. 5 BY MR. HEGARTY: 6 Q. You can answer. |
| 4 5 6 7 8 9 | Q. You can put that document aside. A. Okay. Q. And please look at P6. MR. TISI: How much time do we have? I mean, in light of the fact I did do longer, I'm giving you some leeway. But are we about to land the plane? | 3 Objection. Misstates the document. 4 Misstates the document completely. 5 BY MR. HEGARTY: 6 Q. You can answer. 7 A. Are you referring to the response to |
| 4 5 6 7 8 9 10 | Q. You can put that document aside. A. Okay. Q. And please look at P6. MR. TISI: How much time do we have? I mean, in light of the fact I did do longer, I'm giving you some leeway. | 3 Objection. Misstates the document. 4 Misstates the document completely. 5 BY MR. HEGARTY: 6 Q. You can answer. 7 A. Are you referring to the response to 8 the to the committee? To the to the to 9 the what was it? The the. 10 Q. Citizens |
| 4 5 6 7 8 9 10 11 | Q. You can put that document aside. A. Okay. Q. And please look at P6. MR. TISI: How much time do we have? I mean, in light of the fact I did do longer, I'm giving you some leeway. But are we about to land the plane? | Objection. Misstates the document. Misstates the document completely. BY MR. HEGARTY: Q. You can answer. A. Are you referring to the response to the to the committee? To the to the to the what was it? The the. |
| 4 5 6 7 8 9 10 11 12 | Q. You can put that document aside. A. Okay. Q. And please look at P6. MR. TISI: How much time do we have? I mean, in light of the fact I did do longer, I'm giving you some leeway. But are we about to land the plane? MR. HEGARTY: That's my intent. MR. TISI: Okay. | 3 Objection. Misstates the document. 4 Misstates the document completely. 5 BY MR. HEGARTY: 6 Q. You can answer. 7 A. Are you referring to the response to 8 the to the committee? To the to the to 9 the what was it? The the. 10 Q. Citizens |
| 4 5 6 7 8 9 10 11 12 13 | Q. You can put that document aside. A. Okay. Q. And please look at P6. MR. TISI: How much time do we have? I mean, in light of the fact I did do longer, I'm giving you some leeway. But are we about to land the plane? MR. HEGARTY: That's my intent. MR. TISI: Okay. THE WITNESS: Okay. So P6. | 3 Objection. Misstates the document. 4 Misstates the document completely. 5 BY MR. HEGARTY: 6 Q. You can answer. 7 A. Are you referring to the response to 8 the to the committee? To the to the to 9 the what was it? The the. 10 Q. Citizens 11 A. Citizens Petition? |
| 4 5 6 7 8 9 10 11 12 13 14 | Q. You can put that document aside. A. Okay. Q. And please look at P6. MR. TISI: How much time do we have? I mean, in light of the fact I did do longer, I'm giving you some leeway. But are we about to land the plane? MR. HEGARTY: That's my intent. MR. TISI: Okay. THE WITNESS: Okay. So P6. What am I looking at? | 3 Objection. Misstates the document. 4 Misstates the document completely. 5 BY MR. HEGARTY: 6 Q. You can answer. 7 A. Are you referring to the response to 8 the to the committee? To the to the to 9 the what was it? The the. 10 Q. Citizens 11 A. Citizens Petition? 12 Q. Yes. |
| 4 5 6 7 8 9 10 11 12 13 14 15 | Q. You can put that document aside. A. Okay. Q. And please look at P6. MR. TISI: How much time do we have? I mean, in light of the fact I did do longer, I'm giving you some leeway. But are we about to land the plane? MR. HEGARTY: That's my intent. MR. TISI: Okay. THE WITNESS: Okay. So P6. What am I looking at? BY MR. HEGARTY: | 3 Objection. Misstates the document. 4 Misstates the document completely. 5 BY MR. HEGARTY: 6 Q. You can answer. 7 A. Are you referring to the response to 8 the to the committee? To the to the to 9 the what was it? The the. 10 Q. Citizens 11 A. Citizens Petition? 12 Q. Yes. 13 A. Is that what you're talking about? 14 Q. I am. 15 A. They they made a summary that |
| 4 5 6 7 8 9 10 11 12 13 14 | Q. You can put that document aside. A. Okay. Q. And please look at P6. MR. TISI: How much time do we have? I mean, in light of the fact I did do longer, I'm giving you some leeway. But are we about to land the plane? MR. HEGARTY: That's my intent. MR. TISI: Okay. THE WITNESS: Okay. So P6. What am I looking at? | 3 Objection. Misstates the document. 4 Misstates the document completely. 5 BY MR. HEGARTY: 6 Q. You can answer. 7 A. Are you referring to the response to 8 the to the committee? To the to the to 9 the what was it? The the. 10 Q. Citizens 11 A. Citizens Petition? 12 Q. Yes. 13 A. Is that what you're talking about? 14 Q. I am. |
| 4 5 6 7 8 9 10 11 12 13 14 15 16 17 | Q. You can put that document aside. A. Okay. Q. And please look at P6. MR. TISI: How much time do we have? I mean, in light of the fact I did do longer, I'm giving you some leeway. But are we about to land the plane? MR. HEGARTY: That's my intent. MR. TISI: Okay. THE WITNESS: Okay. So P6. What am I looking at? BY MR. HEGARTY: Q. That is the 1999 study. A. Got it. Yep. | 3 Objection. Misstates the document. 4 Misstates the document completely. 5 BY MR. HEGARTY: 6 Q. You can answer. 7 A. Are you referring to the response to 8 the to the committee? To the to the to 9 the what was it? The the. 10 Q. Citizens 11 A. Citizens Petition? 12 Q. Yes. 13 A. Is that what you're talking about? 14 Q. I am. 15 A. They they made a summary that |
| 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 | Q. You can put that document aside. A. Okay. Q. And please look at P6. MR. TISI: How much time do we have? I mean, in light of the fact I did do longer, I'm giving you some leeway. But are we about to land the plane? MR. HEGARTY: That's my intent. MR. TISI: Okay. THE WITNESS: Okay. So P6. What am I looking at? BY MR. HEGARTY: Q. That is the 1999 study. A. Got it. Yep. Q. Turning over to Table III on page | 3 Objection. Misstates the document. 4 Misstates the document completely. 5 BY MR. HEGARTY: 6 Q. You can answer. 7 A. Are you referring to the response to 8 the to the committee? To the to the to 9 the what was it? The the. 10 Q. Citizens 11 A. Citizens Petition? 12 Q. Yes. 13 A. Is that what you're talking about? 14 Q. I am. 15 A. They they made a summary that 16 they did not feel there was evidence to put a |
| 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 | Q. You can put that document aside. A. Okay. Q. And please look at P6. MR. TISI: How much time do we have? I mean, in light of the fact I did do longer, I'm giving you some leeway. But are we about to land the plane? MR. HEGARTY: That's my intent. MR. TISI: Okay. THE WITNESS: Okay. So P6. What am I looking at? BY MR. HEGARTY: Q. That is the 1999 study. A. Got it. Yep. | 3 Objection. Misstates the document. 4 Misstates the document completely. 5 BY MR. HEGARTY: 6 Q. You can answer. 7 A. Are you referring to the response to 8 the to the committee? To the to the to 9 the what was it? The the. 10 Q. Citizens 11 A. Citizens Petition? 12 Q. Yes. 13 A. Is that what you're talking about? 14 Q. I am. 15 A. They they made a summary that 16 they did not feel there was evidence to put a 17 warning on or to recommend a warning on the |
| 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 | Q. You can put that document aside. A. Okay. Q. And please look at P6. MR. TISI: How much time do we have? I mean, in light of the fact I did do longer, I'm giving you some leeway. But are we about to land the plane? MR. HEGARTY: That's my intent. MR. TISI: Okay. THE WITNESS: Okay. So P6. What am I looking at? BY MR. HEGARTY: Q. That is the 1999 study. A. Got it. Yep. Q. Turning over to Table III on page | 3 Objection. Misstates the document. 4 Misstates the document completely. 5 BY MR. HEGARTY: 6 Q. You can answer. 7 A. Are you referring to the response to 8 the to the committee? To the to the to 9 the what was it? The the. 10 Q. Citizens 11 A. Citizens Petition? 12 Q. Yes. 13 A. Is that what you're talking about? 14 Q. I am. 15 A. They they made a summary that 16 they did not feel there was evidence to put a 17 warning on or to recommend a warning on the 18 product. That is what they said. |
| 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 | Q. You can put that document aside. A. Okay. Q. And please look at P6. MR. TISI: How much time do we have? I mean, in light of the fact I did do longer, I'm giving you some leeway. But are we about to land the plane? MR. HEGARTY: That's my intent. MR. TISI: Okay. THE WITNESS: Okay. So P6. What am I looking at? BY MR. HEGARTY: Q. That is the 1999 study. A. Got it. Yep. Q. Turning over to Table III on page 354. | 3 Objection. Misstates the document. 4 Misstates the document completely. 5 BY MR. HEGARTY: 6 Q. You can answer. 7 A. Are you referring to the response to 8 the to the committee? To the to the to 9 the what was it? The the. 10 Q. Citizens 11 A. Citizens Petition? 12 Q. Yes. 13 A. Is that what you're talking about? 14 Q. I am. 15 A. They they made a summary that 16 they did not feel there was evidence to put a 17 warning on or to recommend a warning on the 18 product. That is what they said. 19 Q. And you're aware from whatever |
| 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 | Q. You can put that document aside. A. Okay. Q. And please look at P6. MR. TISI: How much time do we have? I mean, in light of the fact I did do longer, I'm giving you some leeway. But are we about to land the plane? MR. HEGARTY: That's my intent. MR. TISI: Okay. THE WITNESS: Okay. So P6. What am I looking at? BY MR. HEGARTY: Q. That is the 1999 study. A. Got it. Yep. Q. Turning over to Table III on page 354. A. Yes. Q. You did not find in the middle part of that table a trend for years of use or total | 3 Objection. Misstates the document. 4 Misstates the document completely. 5 BY MR. HEGARTY: 6 Q. You can answer. 7 A. Are you referring to the response to 8 the to the committee? To the to the to 9 the what was it? The the. 10 Q. Citizens 11 A. Citizens Petition? 12 Q. Yes. 13 A. Is that what you're talking about? 14 Q. I am. 15 A. They they made a summary that 16 they did not feel there was evidence to put a 17 warning on or to recommend a warning on the 18 product. That is what they said. 19 Q. And you're aware from whatever 20 sources of information that no talcum powder |
| 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 | Q. You can put that document aside. A. Okay. Q. And please look at P6. MR. TISI: How much time do we have? I mean, in light of the fact I did do longer, I'm giving you some leeway. But are we about to land the plane? MR. HEGARTY: That's my intent. MR. TISI: Okay. THE WITNESS: Okay. So P6. What am I looking at? BY MR. HEGARTY: Q. That is the 1999 study. A. Got it. Yep. Q. Turning over to Table III on page 354. A. Yes. Q. You did not find in the middle part of that table a trend for years of use or total | 3 Objection. Misstates the document. 4 Misstates the document completely. 5 BY MR. HEGARTY: 6 Q. You can answer. 7 A. Are you referring to the response to 8 the to the committee? To the to the to 9 the what was it? The the. 10 Q. Citizens 11 A. Citizens Petition? 12 Q. Yes. 13 A. Is that what you're talking about? 14 Q. I am. 15 A. They they made a summary that 16 they did not feel there was evidence to put a 17 warning on or to recommend a warning on the 18 product. That is what they said. 19 Q. And you're aware from whatever 20 sources of information that no talcum powder 21 product in the United States let me start |
| 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 | Q. You can put that document aside. A. Okay. Q. And please look at P6. MR. TISI: How much time do we have? I mean, in light of the fact I did do longer, I'm giving you some leeway. But are we about to land the plane? MR. HEGARTY: That's my intent. MR. TISI: Okay. THE WITNESS: Okay. So P6. What am I looking at? BY MR. HEGARTY: Q. That is the 1999 study. A. Got it. Yep. Q. Turning over to Table III on page 354. A. Yes. Q. You did not find in the middle part of that table a trend for years of use or total | 3 Objection. Misstates the document. 4 Misstates the document completely. 5 BY MR. HEGARTY: 6 Q. You can answer. 7 A. Are you referring to the response to 8 the to the committee? To the to the to 9 the what was it? The the. 10 Q. Citizens 11 A. Citizens Petition? 12 Q. Yes. 13 A. Is that what you're talking about? 14 Q. I am. 15 A. They they made a summary that 16 they did not feel there was evidence to put a 17 warning on or to recommend a warning on the 18 product. That is what they said. 19 Q. And you're aware from whatever 20 sources of information that no talcum powder 21 product in the United States let me start 22 again. |

| | Page 526 | | Page 528 |
|--|--|----------|--|
| 1 | Q. Are you aware that FDA has not | 1 | you'll give me, and then I will limit it |
| 2 | required an ovarian cancer warning on any talcum | 2 | to that. That's all I can do. |
| 3 | powder product? | 3 | MR. TISI: As long as you tell |
| 4 | MR. TISI: Objection. | 4 | your colleagues that I did. |
| 5 | THE WITNESS: I am not aware | 5 | MS. PARFITT: Give back. Give |
| 6 | that they have. | 6 | back to us, Mark. Not everybody is |
| 7 | BY MR. HEGARTY: | 7 | MR. HEGARTY: Sure. So what |
| 8 | Q. You can put that document aside. | 8 | do you want? Just tell me what you're |
| 9 | MR. TISI: I kind of feel like | 9 | going to give me. |
| 10 | the plane should be landing. | 10 | MR. TISI: I'll give you five |
| 11 | MR. HEGARTY: I'm simply | 11 | minutes. |
| 12 | | 12 | MR. HEGARTY: Okay. Give me |
| 13 | | 13 | five minutes. Okay. |
| 14 | MR. TISI: I understand that. | 14 | BY MR. HEGARTY: |
| 15 | | 15 | Q. Looking at your conflict of interest |
| 16 | | | disclosure in your letter to the editor? |
| 17 | | 17 | A. Yes. |
| 18 | - | 18 | Q. You did not make any reference in |
| 19 | - | 19 | that conflict of interest disclosure that the |
| 20 | • | | consultation you were doing was in connection with |
| 21 | find out how much time we have. | | litigation? |
| 22 | | 22 | MR. TISI: Objection. |
| 23 | | 23 | Objection. Assumes facts. We went we |
| 24 | | 24 | did go through this like in a lot of |
| | Page 527 | | Page 529 |
| 1 | MR. HEGARTY: Yeah. | 1 | detail earlier. |
| 2 | | 2 | BY MR. HEGARTY: |
| 3 | | 3 | Q. I'm just simply asking you to look |
| 4 | | _ | at the words of the disclosure itself and tell me |
| 5 | | | whether you made you reported in that |
| 6 | | | disclosure that the consultation work you did wa |
| 7 | · | | in connection with litigation. |
| 8 | | 8 | MR. TISI: But he indicated he |
| 9 | | 9 | didn't know he was going to be in |
| 10 | | 10 | litigation. |
| 11 | | 11 | THE WITNESS: No, no, no. It |
| 12 | | 12 | was not it was my conflict is that |
| 13 | | 13 | I was serving as a consultant on the |
| 14 | · · · · · · · · · · · · · · · · · · · | 14 | topic of tale and ovarian cancer risk. |
| 15 | | 15 | It was I it was it may |
| 16 | • | 16 | or may not have resulted in litigation. |
| 17 | | 17 | I don't know. I was not an expert |
| 18 | e | 18 | witness. |
| 19 | • | | BY MR. HEGARTY: |
| 20 | | 20 | Q. Your consultation, though, was with |
| | • | | attorneys representing plaintiffs? |
| 2.1 | in in the state of | | · · · · · · · · · · · · · · · · · · · |
| 21 22 | of this. I will just give me if | 22 | A. That's correct. |
| 212223 | ş e | 22 23 | A. That's correct.Q. Okay. You were asked about Hopkins |

| 1 | P 500 | | D 500 |
|--|---|--|--|
| 1 | Page 530 Do you know the source of that | 1 | Page 532 |
| $\frac{1}{2}$ | • | 2 | whether that information might be available if I wanted to see it. |
| $\frac{2}{3}$ | A. Oh, in my in my report. | _ | BY MR. HEGARTY: |
| l . | | 3 | |
| 4 | Q. In your report.A. Yeah. No, other than the reference | 4 | Q. But as far as your review of this, |
| 5 | • | 5 | with regard to your review of this document, you |
| 6 | • | 6 | did not see any of the authorities that the EPA |
| 7 | This is this is Footnote B, correct? | 7 | relied upon, correct? |
| | | 8 | A. I did not. |
| 9 | MR. TISI: Yes. BY MR. HEGARTY: | 9 | Q. You told me earlier in the day that |
| | | | one of the standards for which you applied in your |
| 11 12 | Q. Yes. A. Yeah. | | report as to whether you would comment on an |
| | | | analysis in your paper was they had to show you |
| 13 14 | (Reviews document.) | | the analysis that they did, correct? A. That is correct but |
| | Yeah. Yeah. And I recognize that | 14 | |
| 16 | it was an exhibit from a deposition. Q. You were asked about final set of | 15 | MR. TISI: Objection. |
| 1 | ~ | 16 | THE WITNESS: But |
| 18 | questions. | 17 | MR. TISI: This is for a |
| | You were asked about Exhibit P9, | 18 | different reason. Now, go ahead. |
| | correct? | 19 | BY MR. HEGARTY: |
| $\begin{vmatrix} 20 \\ 21 \end{vmatrix}$ | A. Yes, the EPA report. | 20 | Q. And then |
| | Q. And when did you review this exhibit for the first time? | 21 | MR. TISI: He testified on a |
| 23 | | 22 | causal analysis. This is just biologic |
| | A. I just saw it a few I think I | 23 24 | plausibility. I mean, he testified to |
| 24 | think I might have seen it Friday. | 24 | that. |
| 1 | Page 531 | | Page 533 |
| $\frac{1}{2}$ | Q. Was that provided to you by | 1 | BY MR. HEGARTY: |
| | plaintiffs' counsel? | 2 | Q. Please answer. I think you were |
| 3 | A. Yes, it was. | | starting to answer my question. Go ahead. |
| 4 | Q. Did you make a request for it | 4 | A. I was going to answer that the |
| | initially? | | response to the citizen committee was not |
| 6 | A. No, I did not. | | something that came out in the Federal Register |
| 7 | Q. You have reviewed this document, | | for public observation to make a position stance |
| 1 | correct? | | on the part of the FDA. |
| 9 | A. I haven't reviewed every bit of the | 10 | It was my understanding in response |
| 111 | page, but I've reviewed the summaries on it. | | to a petition as to whether they would approve the |
| 11 | Q. Nowhere in this document does EPA cite to any published or otherwise literature that | | labeling of of risk of talc on a cosmetic talc |
| 12 | che to any published of otherwise interactife that | 12 | product. This is in the Federal Register. |
| 1 | * * | | i nis is ni me rederal kegister |
| 13 | it reviewed with regard to its statements as it | | |
| 13 14 | it reviewed with regard to its statements as it relates to asbestos and ovarian cancer or talc and | 14 | (Indicates). This is a mandate essentially, in my |
| 13 14 15 | it reviewed with regard to its statements as it relates to asbestos and ovarian cancer or talc and ovarian cancer, correct? | 14 15 | (Indicates). This is a mandate essentially, in my view, from the EPA and I it feels different to |
| 13 14 15 16 | it reviewed with regard to its statements as it relates to asbestos and ovarian cancer or talc and ovarian cancer, correct? MR. TISI: Objection. | 14 15 16 | (Indicates). This is a mandate essentially, in my view, from the EPA and I it feels different to me. |
| 13 14 15 16 17 | it reviewed with regard to its statements as it relates to asbestos and ovarian cancer or talc and ovarian cancer, correct? MR. TISI: Objection. THE WITNESS: Yeah. I I | 14 15 16 17 | (Indicates). This is a mandate essentially, in my view, from the EPA and I it feels different to me. Q. So |
| 13 14 15 16 17 18 | it reviewed with regard to its statements as it relates to asbestos and ovarian cancer or talc and ovarian cancer, correct? MR. TISI: Objection. THE WITNESS: Yeah. I I don't well, I'd have to look to see if | 14 15 16 17 18 | (Indicates). This is a mandate essentially, in my view, from the EPA and I it feels different to me. Q. So A. This feels different to me. |
| 13 14 15 16 17 18 19 | it reviewed with regard to its statements as it relates to asbestos and ovarian cancer or talc and ovarian cancer, correct? MR. TISI: Objection. THE WITNESS: Yeah. I I don't well, I'd have to look to see if they provided a citation on this report, | 14 15 16 17 18 19 | (Indicates). This is a mandate essentially, in my view, from the EPA and I it feels different to me. Q. So A. This feels different to me. Q. So with regard to P9, this would be |
| 13 14 15 16 17 18 19 20 | it reviewed with regard to its statements as it relates to asbestos and ovarian cancer or talc and ovarian cancer, correct? MR. TISI: Objection. THE WITNESS: Yeah. I I don't well, I'd have to look to see if they provided a citation on this report, but things that come out of the Federal | 14 15 16 17 18 19 20 | (Indicates). This is a mandate essentially, in my view, from the EPA and I it feels different to me. Q. So A. This feels different to me. Q. So with regard to P9, this would be an authority you would feel would meet your |
| 13 14 15 16 17 18 19 20 21 | it reviewed with regard to its statements as it relates to asbestos and ovarian cancer or talc and ovarian cancer, correct? MR. TISI: Objection. THE WITNESS: Yeah. I I don't well, I'd have to look to see if they provided a citation on this report, but things that come out of the Federal Register are do not typically have | 14 15 16 17 18 19 20 21 | (Indicates). This is a mandate essentially, in my view, from the EPA and I it feels different to me. Q. So A. This feels different to me. Q. So with regard to P9, this would be an authority you would feel would meet your methodology standards for including a discussion |
| 13 14 15 16 17 18 19 20 21 22 | it reviewed with regard to its statements as it relates to asbestos and ovarian cancer or talc and ovarian cancer, correct? MR. TISI: Objection. THE WITNESS: Yeah. I I don't well, I'd have to look to see if they provided a citation on this report, but things that come out of the Federal Register are do not typically have those kinds of references. | 14 15 16 17 18 19 20 21 22 | (Indicates). This is a mandate essentially, in my view, from the EPA and I it feels different to me. Q. So A. This feels different to me. Q. So with regard to P9, this would be an authority you would feel would meet your methodology standards for including a discussion about it in your report; is that correct? |
| 13 14 15 16 17 18 19 20 21 | it reviewed with regard to its statements as it relates to asbestos and ovarian cancer or talc and ovarian cancer, correct? MR. TISI: Objection. THE WITNESS: Yeah. I I don't well, I'd have to look to see if they provided a citation on this report, but things that come out of the Federal Register are do not typically have those kinds of references. Oh, no, like yeah. I don't | 14 15 16 17 18 19 20 21 | (Indicates). This is a mandate essentially, in my view, from the EPA and I it feels different to me. Q. So A. This feels different to me. Q. So with regard to P9, this would be an authority you would feel would meet your methodology standards for including a discussion |

| | Page 534 | 1 | Page 536 |
|----------------------|--|----------------------------|--|
| 1 | is what appears to me is a mandate that | 1 | |
| 2 | has been put forward by a federal agency. | 2 | |
| 3 | It is different from what I saw in that | 3 | |
| 4 | FDA response to a citizens committee. | 4 | |
| 5 | I would hope that a mandate | 5 | 1 |
| 6 | such as this would be backed by evidence, | 6 | |
| 7 | and given that it says it's its final | 7 | MR. TISI: Right. |
| 8 | rule, I would assume that there were | 8 | MR. HEGARTY: And will not |
| 9 | there were iterative processes that it | 9 | reach agreement I'm sure today on our |
| 10 | went through in order to be able to come | 10 | objections or your response. So |
| 11 | up with these this summary. | 11 | MR. TISI: I understand. |
| 12 | BY MR. HEGARTY: | 12 | MR. HEGARTY: I guess that |
| 13 | Q. Going back to my question. | 13 | will be it. |
| 14 | Would it meet your standard that you | 14 | MR. TISI: Thank you. |
| 15 | applied for preparing your report | 15 | |
| 16 | A. If there was no | 16 | (Signature not waived, the |
| 17 | Q to include an analysis in your | 17 | deposition concluded at 8:21 p.m.) |
| 18 | report? | 18 | |
| 19 | A. Yeah. If there was no background | 19 | * * * |
| | information that I could find to support this, | 20 | |
| | then it would not meet my standard. | 21 | |
| 22 | MR. HEGARTY: Okay. All | 22 | |
| 23 | right. Given the time that I've been | 23 | |
| 24 | allowed, those are all the questions that | 24 | |
| | ^ | | |
| 1 | Page 535 I have. | | Page 537 |
| 2 | I'll reiterate my objection to | 1 2 | ERRATA SHEET |
| 3 | the extent that Dr. Harlow was asked | | Page NoLine NoChange to: |
| 4 | about a question about materials that | <i>3</i> | rage NoLine NoChange to |
| 5 | have not previously been disclosed that | | |
| 6 | he would include as a basis for his | 3 | Page NoLine NoChange to: |
| 7 | opinions, that we reserve the right to | 6 | |
| 8 | seek additional time to the extent | | Page NoLine NoChange to: |
| 9 | warranted. | | Page NoLine NoChange to: |
| 10 | MR. TISI: We, obviously, | | |
| 11 | object to that. I've given you more than | | P. V. J. V. G. |
| 12 | enough time. All the documents that you | | Page NoLine NoChange to: |
| 13 | | | |
| 13 | have were in the Dropbox. We provided them several days in advance. These are | | Page NoLine NoChange to: |
| 15 | not new opinions. | | |
| | * | | Page NoLine NoChange to: |
| 16 | These are documents that came | | |
| 17 | out recently and we further support the | | Page NoLine NoChange to: |
| 18 | | 10 | |
| | opinions that you already have. And you | | |
| 19 | asked him whether or not any particular | 19 | Page NoLine NoChange to: |
| 19 20 | asked him whether or not any particular agency had said that talc with asbestos | 19 20 | Page NoLine NoChange to: |
| 19 20 21 | asked him whether or not any particular agency had said that talc with asbestos causes cancer. You asked him the | 19 20 21 | Page NoLine NoChange to: Page NoLine NoChange to: |
| 19 20 21 22 | asked him whether or not any particular agency had said that talc with asbestos causes cancer. You asked him the question. | 19 20 21 22 | Page NoLine NoChange to: Page NoLine NoChange to: |
| 19 20 21 | asked him whether or not any particular agency had said that talc with asbestos causes cancer. You asked him the | 19 20 21 22 23 | Page NoLine NoChange to: Page NoLine NoChange to: |

Document 33295-64 PageID: 260850 Page 538 DECLARATION UNDER PENALTY OF PERJURY 1 2 3 4 I declare under penalty of 5 perjury that I have read the entire transcript of 6 my Deposition taken in the captioned matter 7 or the same has been read to me, and 8 the same is true and accurate, save and 9 except for changes and/or corrections, if 10 any, as indicated by me on the DEPOSITION 11 ERRATA SHEET hereof, with the understanding 12 that I offer these changes as if still under 13 oath. 14 15 Signed on the _____ day of 16 _, 2024. 17 18 19 BERNARD L. HARLOW, PHD 20 21 22 23 24 Page 539 CERTIFICATE OF REPORTER 1 2 DISTRICT OF COLUMBIA) 3 I, Denise Dobner Vickery, a 4 Registered Court Reporter and Notary Public of 5 the District of Columbia, do hereby certify that 6 the witness was first duly sworn by me. 7 I do further certify that the 8 foregoing is a verbatim transcript of the testimony as taken stenographically by me at the 10 time, place and on the date herein set forth, to 11 the best of my ability. 12 I do further certify that I am 13 neither a relative nor employee nor counsel of 14 any of the parties to this action, and that I am 15 neither a relative nor employee of such counsel, 16 and that I am not financially interested in the 17 outcome of this action. 18

Denise D. Vickery

Notary Public in and for the

District of Columbia

24 My Commission expires: March 14, 2028

DENISE DOBNER VICKERY, CRR,RMR

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Federal Rules of Civil Procedure Rule 30

- (e) Review By the Witness; Changes.
- (1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:
- (A) to review the transcript or recording; and
- (B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.
- (2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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